In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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Not to be Published

JOHN DOE/05 and JANE DOE/05, on behalf of CHILD DOE/05,	*	
Petitioners,	*	
v.	*	Onset issue; testimony not credible
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Paul S. Dannenberg, Huntington, VT, for petitioners.
Nathaniel J. McGovern, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ONSET[1]

On February 17, 2004, petitioners filed a petition under the National Childhood Vaccine

[1] Because this unpublished Ruling on Onset contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished Ruling on Onset on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. Petitioners so moved and the Ruling on Onset is redacted.

Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that their daughter (hereinafter, "Child Doe/05"), was injured from receiving acellular DPT and HiB vaccine on March 26, 2001. The petition is silent as to the onset of Child Doe/05's alleged seizures. It is also silent as to any other type of reaction to her vaccinations.

FACTS

Child Doe/05 was born on September 8, 2000. Child Doe/05 is Jane Doe/05's third child.

Twelve days after she was born, Child Doe/05 saw Dr. Thomas C. Johnston, her pediatrician, on September 20, 2000. Med. recs. at Ex. A, p. 7. Child Doe/05 had been sleeping poorly at night, waking every two to three hours. She had severe diaper dermatitis with satellite lesions in the perineum. *Id.*

Eight days later, on September 28, 2000, Jane Doe/05 telephoned Dr. Johnston about the diaper rash. *Id.* Child Doe/05 had been up all night with discomfort. Jane Doe/05 had tried everything. Dr. Jon R. Jolles referred Jane Doe/05 to a dermatologist and she saw Dr. Saad who gave her zinc oxide and recommended Child Doe/05 go back to Enfamil with iron. *Id.*

Four days later, on October 2, 2000, Jane Doe/05 telephoned Dr. Johnston. Med. recs. at Ex. A, p. 8. She began Child Doe/05 on Enfamil with iron on Saturday and now Child Doe/05 was spitting up most of her feeding, but seemed to like this formulas better. Dr. Johnston suggested adding one tablespoon of rice cereal to each bottle and to call if Child Doe/05 had no improvement or Jane Doe/05 had concerns. *Id.*

Two weeks later, on October 16, 2000, Jane Doe/05 telephoned Dr. Johnston. *Id.* Child Doe/05 was very colicky. Jane Doe/05 had tried multiple formulas. She had not tried Alimentum formula yet. Child Doe/05 was still quite fussy. Dr. Johnston recommended Jane

Doe/05 try some Zantac 1 cc. twice daily and he would see Child Doe/05 in a week or two. He discussed the possibility of using Nutramigen or Alimentum if this did not work. *Id.*

One day later, on October 17, 2000, Child Doe/05 saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 6. She had been fine until three weeks of age and, then, in the last couple of weeks, Child Doe/05 had been miserable. She was up at night crying. She had very colicky behavior, pulling her legs up and refluxing with spitting after almost every feeding, especially at night. Jane Doe/05 had tried multiple formula, including soy and cow's milk. Child Doe/05 was currently on Carnation good start. Jane Doe/05 did try to feed cereal to Child Doe/05 but Child Doe/05 would not eat the formula with cereal in it. Dr. Johnston's assessment was that Child Doe/05's behavior was very compatible with gastroesophageal reflux. He advised continuing Child Doe/05 on Zantac and to try Nutramigen for one week. He gave samples to Jane Doe/05. If Child Doe/05 did not improve, she might need a referral for a gastrointestinal clinic. It was all right to try some oatmeal in her bottle rather than cereal. *Id.*

On October 25, 2000, Tufts authorized Nutramigen for up to one year of age. *Id.*

On November 1, 2000, Jane Doe/05 told Dr. Johnston that Child Doe/05 had been up the prior night with a croupy cough, but no fever. She was fussy. *Id.* Child Doe/05 saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 10. She had reflux, and intolerance to cow's milk and soy. She was on Nutramigen. Her sister had a cold and, the prior night, Child Doe/05 was up with a croupy cough but no fever. She was a little bit fussy but still eating quite well. She did not have vomiting or diarrhea. Jane Doe/05 wanted Child Doe/05 checked. Child Doe/05 had still been miserable but no more miserable than before. Child Doe/05 had a mild cough in the office. Dr. Johnston's impression was Child Doe/05 had a cold with cough. He

suggested a humidifier, bulb suction of her nose, and an upright position. *Id.*

On November 1, 2000, at 10:45 p.m., Child Doe/05 was brought to South Shore Hospital Emergency Department by ambulance because of difficulty breathing. Med. recs. at Ex. C, p. 212. She was on thickened Nutramigen and reflux precautions were being taken. Med. recs. at Ex. C, p. 211. The history petitioners gave was that, at 2:00 a.m., Child Doe/05 had a cough and increased trouble breathing. Med. recs. at Ex. C, p. 213. She had decreased oral intake. She had been coughing all day and, that night, she was gasping for breath. She had vomited once and had wet diapers. She had no fever or diarrhea. Her history included reflux and thickened Nutramigen. The diagnosis was bronchiolitis. *Id.* The medical personnel prescribed a shower, vaporizer, Vicks on Child Doe/05's chest, and Tagamet. Dr. June Hanly wrote the report. Med. recs. at Ex. C, p. 214. Jane Doe/05 said that Child Doe/05 had only had problems with reflux before this morning when she had a cough. The cough got much worse and her oral intake was down. She vomited once and seemed to have trouble breathing. Her parents called an ambulance but, when Child Doe/05 got outside in the ambulance, her breathing got much better. Child Doe/05 had no fever although her parents were giving her Tylenol with cold medicine. They stopped that at 4:00 p.m. She had normal bowel movements. Her wet diapers were not as wet. Her eight-year-old sibling had a cold. Child Doe/05 was on Tagamet. She was being treated for reflux with Tagamet, Nutramigen, and thickened feedings. Her temperature was 99.5º. Child Doe/05 had mild retractions. She had diffuse intermittent expiratory wheezes. Neurologically, she was within normal limits. *Id.* Dr. Hanly's differential diagnoses were upper respiratory infection versus bronchiolitis versus pneumonia. Med. recs. at Ex. C, p. 215. Child Doe/05 was given 0.25 Albuterol nebulizer every four hours. Her chest x-ray showed mild

hyperinflation. Because petitioners were very worried about Child Doe/05's breathing at home, she was kept overnight for observation. *Id.* Child Doe/05's five-year-old sibling had asthma. Med. recs. at Ex. C, p. 224. The family had a cat and a dog. *Id.* Child Doe/05 was admitted to South Shore Hospital at 12:05 a.m. on November 2, 2000. Med. recs. at Ex. C, p. 228. Petitioners were with her. Child Doe/05 was easily consoled with a bottle. She had an occasional dry, harsh-sounding cough. She was sleeping and comfortable. *Id.* At 2:00 p.m., Child Doe/05 was bulb-suctioned for white nasal discharge. She had no respiratory distress. She was alert and happy. *Id.* At 4:30 p.m., her breath sounds were clear. She had slight congestion and a cough. She took feeds well. She was discharged home on a nebulizer. Med. recs. at Ex. C, p. 229.

Two days later, on November 3, 2000, Jane Doe/05 telephoned Dr. Johnston. *Id.* She was using a nebulizer every four to six hours. Child Doe/05 was discharged from South Shore Hospital the prior night with a diagnosis of bronchiolitis. Child Doe/05 was doing well. *Id.*

Three days later, on November 6, 2000, Jane Doe/05 telephoned Dr. Johnston. Med. recs. at Ex. A, p. 9. Jane Doe/05 was using a nebulizer every four hours because Child Doe/05 was coughing a lot. He prescribed Albuterol solution 20 cc 0.5% and 0.25 ml with 2 ml of sodium chloride via nebulizer every four hours. *Id.*

Three days later, on November 9, 2000, Jane Doe/05 telephoned Dr. Johnston. *Id.* She had taken Child Doe/05 to the dermatologist Dr. Saad because of her irritative rash. He gave her a sample. *Id.*

Five days later, on November 14, 2000, Jane Doe/05 told Dr. Johnston that Child Doe/05 still had a cough, but no fever. Med. recs. at Ex. A, p. 10. Child Doe/05 saw Dr. Johnston for a

sick visit. Med. recs. at Ex. A, p. 9. She had a history of cold symptoms. She had been admitted to the hospital overnight a couple of weeks earlier. She still had a cough but no fever. Jane Doe/05 wanted her checked. Dr. Johnston examined Child Doe/05 and found her normal. His impression was she still had an upper respiratory infection. *Id.*

Four days later, on November 18, 2000, Jane Doe/05 told Dr. Johnston that Child Doe/05 was up at night, cranky, and had vomited the day before. Med. recs. at Ex. A, p. 11. Child Doe/05 saw Dr. Johnston. This was also her two-month visit. *Id.* She had a little stuffiness lately and was still colicky and still spitting. She was on Nutramigen for this problem. *Id.*

On December 7, 2000, Child Doe/05 saw Dr. Johnston's nurse practitioner Catherine Dennehy. Med. recs. at Ex. A, p. 13. Child Doe/05 had had congestion for about two days with some mucous from her nose for which Jane Doe/05 used the bulb syringe. She used the nebulizer once the prior night and once that day. Child Doe/05 was afebrile. She was fussy, but Child Doe/05 was always fussy. She did not have vomiting or diarrhea. She continued to take only two ounces at a feeding, but this was her normal. Her brother had a cold at home. Child Doe/05's tympanic membranes were grey and mobile. Nurse Dennehy's assessment after examination was an upper respiratory infection. She suggested elevating the head of Child Doe/05's bed and using a vaporizer. *Id.*

On December 18, 2000, Child Doe/05 received her first acellular DPT vaccination after Jane Doe/05 had a lengthy discussion with Dr. Jolles about whether to proceed with the vaccination. Med. recs. at Ex. A, pp. 1, 2. Child Doe/05 saw Dr. Jon R. Jolles, who worked with Dr. Johnston, for a vaccination update. Med. recs. at Ex. A, p. 13. Jane Doe/05 wanted him to check Child Doe/05's ears. Child Doe/05 was always cranky, but did not have fever. Dr. Jolles'

notes record the following conversation:

> **Child Doe/05's brother evidently had a reaction to his DPT**, this was the old formulation. He evidently was **very lethargic** for approximately two days. **He has not received subsequent pertussis shots.** We discussed the risks and benefits of pertussis vaccine including the decreased incidents [sic] of common side effects from the new acellular vaccine, but I stated to Jane Doe/05 that I cannot guarantee the absence of any severe reaction including neurologic damage. After discussion, she elected to go ahead and receive the DTAP and **watch her closely for any reaction**. We will wait on the Prevnar, which I also discussed until the next visit so that we can tell for sure whether there is any reaction to this present shot. [emphasis added].

Dr. Jolles examined Child Doe/05 and found no evidence for ear infection. Her ears and throat were clear. *Id.*

On January 2, 2001, Child Doe/05 saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 12. Jane Doe/05 had Child Doe/05's ears pierced about eight weeks previously. The day before, the left ear lobe got infected and swollen. Jane Doe/05 took the earring out but the lobe was still swollen. On examination, Dr. Johnston saw the infected hole where the earring had been on the left side. Puss was easily expressed. There was some mild surrounding erythema but mostly there was just swelling and tenderness. Dr. Johnston's impression was left infected ear lobe. He prescribed Keflex 125 tid x10 and soaks. He suggested not putting the earring back in. *Id.*

Ten days later, on January 12, 2001, Jane Doe/05 telephoned Dr. Johnston. *Id.* Child Doe/05 had thrush and he prescribed Nystatin oral suspension 1 ml tid x 10 days. *Id.*

Five days later, on January 17, 2001, Child Doe/05 saw Dr. Johnston for a sick visit. *Id.* She had had a tight congested cough and her appetite had been down. She has had thrush and had been using Nystatin with limited success. Child Doe/05's brother had asthma and Jane

Doe/05 was worried about wheezing. On examination, Child Doe/05 was coughing. Her throat showed thrush. Her lungs had occasional wheezes but good air movement. Dr. Johnston's impression was mild bronchiolitis and thrush. He prescribed Gentian violet. Child Doe/05 was to go on a nebulizer at home every four to six hours. *Id.*

On January 23, 2001, Child Doe/05 saw Dr. Johnston for her four-month checkup. Med. recs. at Ex. A, p. 14. She was doing fine overall. She had a little bit of thrush and was still coughing. Her diet was Nutramigen and cereal and she was doing well with that. She was up a lot for a bottle. She had a history of bronchiolitis which came and went. *Id.*

On February 9, 2001, Blue Cross Blue Shield approved Child Doe/05 for Nutramigen for one year. *Id.*

On March 26, 2001, Child Doe/05 received her second acellular DPT vaccination and her third HiB vaccination. Med. recs. at Ex. A, pp. 1, 2. This was during her six-month checkup with Dr. Johnston. Med. recs. at Ex. A, p. 15. She was still on Nutramigen. She also ate oatmeal and several fruits and vegetables. Jane Doe/05 would advance the diet very slowly as Child Doe/05 seemed to have problems with each new food. Child Doe/05 stooled with difficulty at times. Occasionally, she needed some rectal stimulation. Child Doe/05 had not yet rolled over, but was reaching and passing hand to hand. She sat with support. She babbled, cooed, and laughed. Her sleep was poor. Jane Doe/05 told Dr. Johnston that Child Doe/05 was up at least once or twice a night for a bottle. Dr. Johnston recommended Dr. Ferber's book. *Id.*

On April 14, 2001, the day before Easter in 2001, petitioners brought Child Doe/05 to South Shore Hospital Emergency Department at 8:38 a.m. because she had an episode of not breathing. Med. recs. at Ex. C, p. 116. The Emergency Department Flow Sheet notes that

petitioners stated that Child Doe/05 was unresponsive and not breathing for about five minutes. She arrived awake and crying. She had normal color and was alert. She made eye contact and had normal affect. Med. recs. at Ex. C, p. 117. John Doe/05 gave the history to the doctor that Child Doe/05 became motionless, red, and apneic. Her seizure activity lasted about four minutes. She had no recent illness. Her temperature was 98.3º. Med. recs. at Ex. C, p. 118. Her prior medical history was colic. The doctor noted asthma. The doctor's impression was acute life threatening event (ALTE). *Id.* Dr. Michael Hughes wrote that the chief complaint was apnea. John Doe/05 told him that Child Doe/05 became motionless and stopped breathing for about three to four minutes that morning. She was not eating at the time but was just being held. Her parents put her down and called 911. Then Child Doe/05 awoke and started breathing again. John Doe/05 said that Jane Doe/05 noted that Child Doe/05 had an episode like this the day before (April 13, 2001), lasting only several seconds. Child Doe/05 did not have any recent fever, chills, vomiting, or diarrhea. She was not on any medications. Child Doe/05 had no significant history of other illness, other than a slight asthma noted in the past. She did not have shaking or seizure activity. Med. recs. at Ex. C, p. 119. Child Doe/05's temperature was 98.3º. She was awake, alert, and moving all extremities. *Id.* Dr. Hughes' differential diagnoses were apnea, aspiration pneumonia, cardiac arrhythmia, seizure, and sepsis. Med. recs. at Ex. C, p. 120. Child Doe/05 was afebrile and looked well, but Dr. Hughes thought she should be admitted for observation. *Id.*

Child Doe/05 was admitted to South Shore Hospital at 9:56 a.m. on April 14, 2001. Med. recs. at Ex. C, p. 114. Dr. Carol Baum saw Child Doe/05 around noon. Petitioners were Dr. Baum's informants. The chief complaint was that Child Doe/05 went limp and lifeless for

several minutes while lying flat for a diaper change that day at around 7:45 a.m. prior to eating breakfast. Both parents witnessed the event and Jane Doe/05 called 911. John Doe/05 administered two rescue breaths. Child Doe/05 did not seem to be breathing. Her face seemed red, but not purple. Med. recs. at Ex. C, p. 123. Child Doe/05 had some saliva in her oral pharynx but no emesis. She did not have tonic or tonic-clonic movements. Child Doe/05 was otherwise well except for an intermittent cough. She was well-appearing before the event. Her prior medical history was significant for a history of gastroesophageal reflux clinically. She was on thickened Nutramigen feeds. Usually, the head of Child Doe/05's bed was elevated. Child Doe/05 was rarely flat. She received Zantac on an as-needed basis. She had about one to two large bouts of spitting up. On Dr. Baum's further questioning of the parents, Child Doe/05 had two prior episodes that occurred that week while she was lying flat for a diaper change where Child Doe/05 seemed to be not responsive, lasting several seconds and resolving. (The bottom of the medical records is cut off at this point. See P. Ex. T for a duplicate which includes the bottom of the page.) (Since April 14, 2001 was a Saturday, the week would have begun on Sunday, April 8, 2001, 13 days after her vaccination. Therefore, two prior episodes occurring that week would have been between April 8th and 14th, 2001. Petitioners had earlier stated that one prior episode occurred on April 13, 2001.) Child Doe/05 also had bronchiolitis at seven weeks and used a nebulizer. She had a milk protein allergy. She also had a mild rhinorrhea and croupy occasional cough beginning that day. She had normal developmental milestones. Her immunizations were delayed secondary to hospitalization for bronchiolitis. *Id.* Child Doe/05 has a half-sister who had gastroesophageal reflux (GER) as an infant and was on Nutramigen, thickened feeds, and Zantac. Her half-sister outgrew GER at age one and one-half. Med. recs. at

Ex. C, p. 124. Child Doe/05 chronically spit up large volumes of feeds. She had an occasional cough. *Id.* Her general appearance was smiling and non-toxic. Dr. Baum concluded that Child Doe/05 had a normal neurologic examination. Med. recs. at Ex. C, p. 125. Her chest x-ray showed a slight increase in bronchovascular markings but no infiltrate. *Id.* and Ex. C, p. 139. Dr. Baum's assessment was that the most likely diagnosis, given Child Doe/05's history, seemed to be an episode of reflux with vagal stimulation.[2] Other possibilities included seizure, arrhythmias, and broncho/laryngospasm. Med. recs. at Ex. C, p. 126. Child Doe/05 would have a home apnea monitor. Child Doe/05 was to restart Zantac when she was discharged. The head of her bed was to be elevated. She was to have thickened feeds and Nutramigen. *Id.* At 2:30 p.m., Jane Doe/05 told the nurse that she felt as if she were going to be sick and that she had a headache. Med. recs. at Ex. C, p. 128. Child Doe/05 was alert and smiling and her color was pink. *Id.* Jane Doe/05 roomed in and emotional support was provided. *Id.*

On April 15, 2001, at 8:55 a.m., Child Doe/05 was very irritable and Jane Doe/05 was unable to console Child Doe/05 calmly in spite of encouragement to hold her and not bounce her while holding her or while Child Doe/05 was in the infant seat. At 2:30 a.m., Child Doe/05 had a rectal temperature of 100.3º. Med. recs. at Ex. C, p. 129. Child Doe/05 slept in her mother's arms. Jane Doe/05 was reassured and educated numerous times regarding the apnea monitoring alarms and positioning by the nurse and Dr. Baum. Dr. Baum was with Jane Doe/05 and Child Doe/05 from 4:00-5:40 a.m. Child Doe/05 was alert, smiled, and tracked Jane Doe/05 at times

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[2] A vagal or vasovagal attack is "a transient vascular and neurogenic reaction marked by pallor, nausea, sweating, bradycardia, and rapid fall in arterial blood pressure which, when below a critical level, results in loss of consciousness and characteristic electroencephalographic changes." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 178.

when she was not irritable. She slept short naps only. *Id.* At 1:35 p.m., Child Doe/05 did not have a temperature. Med. recs. at Ex. C, p. 130. Zantac was started and Child Doe/05 vomited. A CPR video was shown to Mr. and Jane Doe/05. An apnea monitor was ordered and a technician was in to teach Mr. and Jane Doe/05. *Id.* Child Doe/05 was also on Tagamet (not given daily) and Mylicon drops for gas. Med. recs. at Ex. C, p. 140. Child Doe/05 was discharged from the hospital on April 15, 2001, Easter Sunday. Med. recs. at Ex. C, p. 127.

Two days later, on April 17, 2001, Child Doe/05 saw Dr. Johnston for a sick visit. *Id.* Child Doe/05 had an episode on April 14, 2001 and went to South Shore Hospital for further workup. The episode was a choking/stopping of breathing which occurred after she had been lying on her back while her diaper was being changed. She did not have fever at the time. She came around in several minutes just when the ambulance showed up to take her to South Shore Hospital. Her blood work at the hospital was normal. A pneumogram was also normal. She was watched for 24 hours and sent home. She was on a monitor. Jane Doe/05 was concerned about the possibility of a seizure. Dr. Johnston said he would arrange for a sleep-deprived EEG in the near future. Child Doe/05's physical examination was normal. She was neurologically normal. Dr. Johnston's impression was possible choking episode or vasovagal response. He needed to rule out seizure with an EEG and continue with the monitor. *Id.*

On April 18, 2001, Dr. Johnston telephoned Jane Doe/05. Med. recs. at Ex. A, p. 16. Jane Doe/05 had telephoned her cousin, a pediatric gastroenterologist in Utah, who recommended Reglan for Child Doe/05's reflux. Dr. Johnston could not disagree although he preferred to use Cisipride, although it was off the market due to arrhythmias. He would start Child Doe/05 on Reglan at .1 mg/kilo per dose which worked out to .8 mg per dose 30 minutes

prior to feeding. *Id.*

On April 24, 2001, Dr. Johnston telephoned Jane Doe/05. *Id.* Dr. Davis read the EEG as completely normal. There was no evidence that Child Doe/05 had seizures. Child Doe/05 was on Reglan, thick cereal, and Nutramigen. Dr. Johnston recommended gastrointestinal follow-up and referred Child Doe/05 to Dr. Pleskow for evaluation. Child Doe/05 was also on a monitor because of her episode which Dr. Johnston considered to be reflux and possibly aspiration a couple of weeks ago. *Id.*

On April 25, 2001, Dr. Johnston telephoned Jane Doe/05. *Id.* Child Doe/05 had had a couple of episodes that day that lasted about a minute where she appeared to be out of touch with reality, rolling her eyes up the back of her head, without motor movement. Jane Doe/05 did not think that Child Doe/05 had a seizure. Jane Doe/05 had to resuscitate Child Doe/05 by slapping her back several times and then she regained consciousness. There was no cyanosis, shortness of breath, or major problems with color. Dr. Johnston recommended a local work-up and further work-up at Children's Hospital. She had a negative pneumogram, a normal EEG, and normal lab studies. *Id.*

Also on April 25, 2001, Child Doe/05 was brought to Children's Hospital Emergency Department at 3:14 p.m. Med. recs. at Ex. I, p. 3. Jane Doe/05 told them that Child Doe/05 had a history of reflux and one apnea spell. She had had spells for two days. Jane Doe/05 said that Child Doe/05 was well until the day before (April 24th) when she had two spells, lasting 30 seconds to one minute, when she suddenly became limp with her eyes fluttering. Jane Doe/05 rubbed her back and splashed water in her face. After the episode, Child Doe/05 was active and playing. She had no color change, apnea, tonic-clonic jerking, or eye rolling. She had no fever,

vomiting, diarrhea, or cough. Child Doe/05 had two more episodes that day. Three of four episodes occurred within ½ hour of eating. She had no gagging or choking. She was eating well with a baseline amount of spitting up, slightly improved after recent Reglan. On Easter Sunday (one and one-half weeks ago), Child Doe/05 had a spell where she stopped breathing for two to three minutes while lying on the changing table. John Doe/05 gave her two rescue breaths and she began breathing again. She was seen at South Shore Hospital where a pH probe and EEG were done and normal by report. She was discharged home on an apnea monitor with no further episodes. Child Doe/05 had a history of reflux, and was colicky/spitty in early life. She had multiple formula changes. She was on Zantac for several months. She started Reglan five days earlier (April 20, 2001) after her spell one and one-half weeks ago. She had bronchiolitis at one month of age. She was currently taking Reglan and Zantac. She was alert and nontoxic. Her reflexes were normal and she moved all extremities. She was alert and appropriate for age. She had two spells in the Emergency Department. Observers noted Child Doe/05 to become limp with her eyes open, looking down. She did not respond to tactile or visual stimulation. The spells resolved in 30 seconds with Child Doe/05 slightly sleepy afterwards. Dr. Heather M. McLauchlan and Dr. David Greenes consulted with neurology who thought Child Doe/05 could have possible seizures. She was admitted to neurology for observation. A CT scan of her head was normal. She had a lumbar puncture. The assessment was new onset seizures. Dr. Greenes saw Child Doe/05's episode in the Emergency Department where she was staring slightly below midline, could not engage, had no spontaneous movement, her tone was slightly increased in both upper extremities, and she had slight frothy saliva in her mouth. This resolved over 10-15 seconds with resumption of spontaneous movement and no sleepiness. *Id.*

On April 25, 2001, a Neurology consultation in the Emergency Department by a doctor whose signature is illegible states that Child Doe/05 had been in good health except for reflux. Med. recs. at Ex. I, p. 19. She had been a colicky baby. On April 14, 2001, her father witnessed an apneic episode. Child Doe/05 was active and playing and then went limp, her face turning red. John Doe/05 thought she had stopped breathing. They called 911. They patted her on the cheeks and back without response. They gave her a couple of breath. By the time the EMS arrived, Child Doe/05 was breathing normally. She had no abnormal movements and no cyanosis. She was taken to South Shore Hospital and admitted overnight. A pH probe and EEG were reportedly normal. *Id.* An EEG administered on April 26, 2001 was normal. Med. recs. at Ex. I, p. 35.

Child Doe/05 was admitted to Children's Hospital at 3:14 p.m. Med. recs. at Ex. I, p. 9. On April 26, 2001, at 4:15 p.m., Dr. Gary Hsich took the admission history from petitioners. Child Doe/05 was well until April 14, 2001, an episode that John Doe/05 saw. She was active and playing and then went suddenly limp. Her face turned red and she appeared to be apneic. They called 911 and patted her on the cheeks and back without response. John Doe/05 gave her a few breaths through the nose and mouth. When the EMS arrived, Child Doe/05 was breathing normally. Med. recs. at Ex. I, p. 10. She did not have abnormal movements or cyanosis. She was admitted overnight to South Shore Hospital where she had a normal EEG and pH probe. She was started on Reglan. On April 24, 2001, she had two episodes which were somewhat different. One happened shortly after she had been fed. Her eyes opened and she was staring. There was no eye rolling, abnormal movement, or back arching. She was unresponsive for 10-15 seconds. She was okay after one of the episodes and sleepy after the other. On April 25,

2001, she had another two episodes. One occurred 20 minutes after being fed. The other occurred just before eating. They were similar to the episodes on April 24th. In the Emergency Department, Child Doe/05 had another two similar episodes. She was sleepy after the second one. On April 26th, that day, she was still having episodes, mostly after feeding, of staring, limpness, and unresponsiveness, with desaturations to the low 80s, lasting about one minute or less. Then she became sleepy. Petitioners gave a history that she was a colicky baby with a history of reflux since her early weeks. *Id.* John Doe/05's brother had a neonatal brain injury with resultant seizures. Child Doe/05's immunizations were up to date for age. Med. recs. at Ex. I, p. 11. On examination, Child Doe/05 was happy, active, playful, and nondysmorphic. When she had a seizure, she desaturated to the low 80s, went limp, unresponsive, but did not stiffen or twitch. She was sleepy afterward. *Id.* Dr. Hsich's impression was that Child Doe/05 had a normal examination with possible mild motor delay. She had episodes of unresponsiveness suspicious for seizure, but it could also be reflux. Med. recs. at Ex. I, p. 12.

Also on April 26, 2001, Child Doe/05 was seen by Dr. Jonathan T. Megerian. She had had 14 days of intermittent spells of sudden onset alteration in mental status associated with limpness. Med. recs. at Ex. I, p. 15. Her parents did not notice any color change or motor activity. The spells lasted less than one minute, usually 10-15 seconds, followed by excessive fatigue. She had a long history of gastroesophageal reflux treated early on with Zantac, which was decreased about one month earlier because she seemed to be doing better. When her new symptoms began about two weeks ago, her dose of Zantac was put back at the prior dose of 5 mg. Reglan was also begun as it was felt at that time that her spells were most consistent with gastroesophageal reflux. The spells that occurred more recently seemed more severe despite

these medicine changes and were now associated with febrile illness. *Id.* Her fine motor development was appropriate for age. She rolled front to back, but not the reverse. She was not yet able to get to sit or stand, but maintained sitting when placed. She took Nutramigen secondary to intolerance to other formulas. Petitioners did not have complaints of systemic or localized illness or symptoms in the past. Dr. Megerian's assessment was vasovagal syncope. The story sounded most like a reflux-induced spell, e.g., Sandifer's syndrome.[3] Seizures would need to be ruled out with a bedside monitor. Jane Doe/05 should increase Zantac to the appropriate dosage per weight. The second diagnosis was gastroesophageal reflux disease, unchanged, which was the likely cause of Child Doe/05's symptoms. Zantac elixir, 75 mg/5cc 30 mg was started and Reglan 5 mg. tab. *Id.*

On April 27, 2001, Child Doe/05 had no further events with an increase in her Zantac. Med. recs. at Ex. I, p. 14. It was unclear whether she was having gastroesophageal reflux symptoms or seizures. A GI consult was ordered. *Id.*

On April 27, 2001, a gastroenterologist consulted and took a history that Child Doe/05 had initially been on Enfamil for three weeks but changed to Carnation for five days, then switched to Nutramigen, when her colic was much improved. Her primary medical doctor started her on Zantac for eight weeks with some improvement. Two weeks ago, she had an apneic episode lasting three minutes. Most episodes occurred after feeding but occasionally on an empty stomach. Med. recs. at Ex. I, p. 18. An EEG on April 26, 2001 was normal. Dr. Frank H. Duffy stated there were no epileptiform features to suggest an underlying diagnosis of

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[3] Sandifer's syndrome is "intermittent torticollis occurring in children as a symptom of reflux esophagitis or hiatal hernia." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1831.

epilepsy. Med. recs. at Ex. I, p. 35. A bedside EEG on April 27, 2001 was normal. Med. recs. at Ex. I, p. 36.

On April 29, 2001, Dr. Jolles wrote a note that may be the result of a phone call. Med. recs. at Ex. A, p. 17. Child Doe/05 was home from Children's Hospital Medical Center where they diagnosed seizures. She was on Zantac and Reglan. An upper gastrointestinal test result was pending. She was on antibiotics while in the hospital. She had thrush. *Id.*

On May 2, 2001, Jane Doe/05 telephoned Dr. Johnston. *Id.* Child Doe/05's upper gastrointestinal test was normal at Children's Hospital the day before. She remained on Zantac and Reglan. Child Doe/05 would see Dr. Pleskow the next day. There was still no diagnosis for her episodes but they dramatically improved since she increased the dose of Zantac to 2 cc twice a day. *Id.*

On May 3, 2001, Child Doe/05 saw Dr. Randi G. Pleskow, a gastroentologist, at Children's Hospital. Med. recs. at Ex. I, p. 200. She was begun on Zantac at two months of age which was stopped at 5.5 months of age because her spitting improved although it did not stop. About three weeks earlier while on the changing table, Child Doe/05 became cyanotic, lasting about three minutes. She had a 12-hour pH probe at South Shore Hospital and was placed on an apnea monitor. She was started on Zantac at 1 cc. twice a day, and Reglan, 0.8 cc, four times a day. That episode was three hours after her last feed. She seemed to do well until the prior week, when she had several episodes of eye-rolling and became limp. She was admitted to Children's Hospital. She had her Zantac dose increased to 2 cc. twice a day and following that, the episodes stopped. The Reglan was changed to 0.5 cc., four times a day. Her mother was reluctant to feed her baby foods because Child Doe/05 was very irritable for two days after

getting green beans and had been very gassy after certain foods such as peas. *Id.* Dr. Pleskow wondered if Child Doe/05's eye-rolling episodes were associated with Reglan. Med. recs. at Ex. I, p. 201. He recommended changing the Zantac to 1.5 cc three times a day and to restart baby foods. Although he thought the eye-rolling episodes could be secondary to the Reglan, he did not feel comfortable stopping Reglan at that point considering Child Doe/05's apneic episode a few weeks earlier. *Id.*

On May 7, 2001, Child Doe/05 saw Dr. Johnston for follow-up. Med. recs. at Ex. A, p. 18. She had approximately 10 spells of gasping for air. The apnea monitor never went off. Med. recs. at Ex. A, p. 17. Child Doe/05 had a long history of spells which now occurred infrequently and she had done much better over the past week. Med. recs. at Ex. A, p. 18. She had three things done prior to her spells on Sunday (the day before), including taking Mylicon, being put in a bassinet instead of a chair, and being given applesauce. She had about 10 spells the prior day (Sunday) and some were really bad. She was also on Reglan .4 and Zantac 1 ½ cc. On examination, Child Doe/05 was alert, bright, active, and interactive. Dr. Johnston's impression was that her spells were probably related to reflux. His plan was to discard the Mylicon, the bassinet, and all solids except for cereal. Jane Doe/05 was to call him in two days. *Id.*

On May 11, 2001, Child Doe/05 was brought to South Shore Hospital Emergency Department for seizure activity that Jane Doe/05 stated had occurred at home. Med. recs. at Ex. C, p. 92. Child Doe/05 was on Prilosec and Mylanta and she had an apnea monitor. Jane Doe/05 said that Child Doe/05's seizure lasted one minute. She did not have cyanosis or apnea. She had gurgling. When the EMTs arrived, Child Doe/05 was asleep. Jane Doe/05 stated that

this was her usual post-event appearance. She had had 24 similar events since Easter (April 15, 2001). Work-up for seizures was negative. On physical examination, Child Doe/05 moved when touched but was asleep. Her tympanic membranes were red. She had good body tone. Dr. Dwayne E. Greene's impression was a seizure. He would consult with Dr. Johnston and transfer her to New England Medical Center. *Id.* Jane Doe/05 stated that Child Doe/05 was slumped over in her chair, making funny gurgling noises. She arrived at the ER pink, lethargic, and arousable. Jane Doe/05 said she was awake and playful prior to the incident. Med. recs. at Ex. C, p. 93.

On May 12, 2001, Child Doe/05 was taken to Children's Hospital Emergency Department. Med. recs. at Ex. I, p. 192. Dr. Stuart Harris and Dr. Marvin B. Harper noted she had been admitted twice for apneic episodes with reportedly negative seizure workup but with evidence of reflux. She had four minutes of staring off into space followed by bilateral arm and head/neck tonic-clonic activity. Her eyes rolled back in her head and she had grunting shallow breathing. This was followed by slight spitting up and deep sleep. This was her longest episode to date. Since her discharge from Children's Hospital on April 27, 2001, Child Doe/05 had 9-10 episodes on May 5th only, all lasting less than 20 seconds and not accompanied by tonic-clonic activity. All occurred following feeding. That day's episode occurred before feeding. Neurologic consult advised discharge to home and the discontinuance of Reglan as being possibly involved. The assessment was laryngospasm. *Id.* That day, Child Doe/05 was given her Reglan and, two seconds later, her eyes rolled back, she was breathing rapidly, and had clonic movements of both arms and her face. Med. recs. at Ex. I, p. 195. This was different than her previous episodes because she became stiff and her legs were not moving. Afterward, she

went to sleep. *Id.*

On May 18, 2001, the Hull Fire Department EMS was called to take Child Doe/05 to the ER. She was conscious but lethargic. Jane Doe/05 said she was feeding Child Doe/05 when she had a possible seizure. Med. recs. at Ex. C, p. 95. Child Doe/05 was brought to South Shore Hospital Emergency Department for lethargy. Med. recs. at Ex. C, p. 91.

Dr. Dwayne E. Greene took a history from Jane Doe/05 that Child Doe/05 had a one-minute seizure at home. Med. recs. at Ex. C, p. 99. She was seated in a baby chair and Jane Doe/05 had just fed her. Jane Doe/05 went into another room and heard Child Doe/05 gurgling. She came back to find Child Doe/05 shaking all over as if she were having a seizure. This lasted for one minute. There was no cyanosis or apnea. Child Doe/05 would not arouse to tactile stimulus. Jane Doe/05 stated Child Doe/05 had had as many as 24 of these episodes over the past two months. She also stated she is the only person who has witnessed these episodes. A pediatrician, neurologist, and gastroenterologist evaluated Child Doe/05 numerous times. The current theory was reflux or sleep apnea. Jane Doe/05 stated she had a recent change in her Prilosec and Mylanta which did not stop the episodes from occurring. Jane Doe/05 was quite distraught about no one believing her when she stated Child Doe/05 was having seizures. *Id.* On examination, Child Doe/05 was well-developed and well-nourished. She was asleep in her mother's arms and moved when touched but did not awaken. Her tympanic membranes appeared red. She had good body tone. Differential diagnoses included seizure disorder versus sleep apnea versus gastroesophageal reflux versus Munchausen by proxy.[4] Med. recs. at Ex. C,

[4] Factitious disorder by proxy is "a form of factitious disorder in which one person intentionally fabricates or induces signs and symptoms of one or more physical (*Munchausen syndrome by proxy*) ... disorders in another person under their care.... The dyad is usually that of

p. 100. Dr. Greene spoke with Dr. Johnston about his examination and Jane Doe/05's mental condition. Child Doe/05 was transferred to New England Medical Center Floating Hospital for neurologic testing. *Id.*

From May 18-25, 2001, Child Doe/05 was in New England Medical Center. Med. recs. at Ex. B, p. 2. John Doe/05 signed the admitting questionnaire. Med. recs. at Ex. B, p. 66. On May 18, 2001, Dr. Uzme Vhang took a history that Child Doe/05 was an eight-month-old girl with multiple episodes over the past one month of episodes (putting onset in mid-April 2001). Med. recs. at Ex. B, p. 7. Dr. M. Provenca took a history on the same day that Child Doe/05's apnea spells began in mid-April. Med. recs. at Ex. B, p. 6. A senior pediatric resident whose name may be Dr. Feigall wrote a history that Child Doe/05 had about 12 episodes of abnormal behavior over the last one month, usually occurring once in a day. Child Doe/05 would be awake and either go limp with eye fluttering, turn dark red, or occasionally stiffen and arch. She slept for an hour after each episode. Jane Doe/05 was very frustrated since Child Doe/05 had multiple hospital admissions about this problem at South Shore and Children's. Jane Doe/05 said she had been vomiting all day with nerves. Med. recs. at Ex. B, p. 39. The doctor's differential diagnoses included seizure, GERD, Sandifer's syndrome, central apnea, or potential neurologic problems. Med. recs. at Ex. B, p. 40. The only clues were that her presentation was more consistent with reflux. The hoarse cry that Jane Doe/05 said Child Doe/05 had had almost since birth could be a respiratory cause of distress or be consistent with reflux. *Id.*

On May 22, 2001, an ear, nose, and throat doctor whose signature is illegible took a history that Child Doe/05 had 12 episodes of either going limp with eyes fluttering, turning red,

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mother and child." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 548.

or occasionally becoming stiff and arching her back. She then slept for one hour after each episode. This had been occurring on six days over the last month. She had been worked up at South Shore Hospital and Children's. EEG showed no seizure activity, no spells. She had a history of spitting up and thickened feedings. The episodes occurred when she was upright and prone. Prilosec prescribed the prior Tuesday initially helped but the symptoms returned. She was also on Mylanta. Med. recs. at Ex. B, p. 9. Child Doe/05's half-sister and half-brother had reflux. Her history and examination were consistent with reflux although these were only minimal findings. The doctor recommended continuing with anti-reflux medication. *Id.*

On May 23, 2001, Jane Doe/05 conferred with nurse Susanna Hesse and said she thought Child Doe/05 had seizures and she wanted to put Child Doe/05 on anti-seizure medication. The nurse warned her of side effects of seizure medications, but said she would pass on the information to the doctors, which she did. Jane Doe/05 was anxious. Med. recs. at Ex. B, p. 10.

Also on May 23, 2001, the social worker whose name might be Cara Weiner wrote her assessment. Med. recs. at Ex. B, p. 11. Jane Doe/05 had her own hair salon and described Child Doe/05's hospitalization to evaluate her for choking episodes as stressful for her business. Child Doe/05 had her first episode over Easter. Since that time, Child Doe/05 had been hospitalized many times in an attempt to reach a diagnosis, but without success. Jane Doe/05 described feelings of stress and anxiety about Child Doe/05's illness and lack of diagnosis. According to Jane Doe/05, her last choking episode was very traumatic. Jane Doe/05 had to administer CPR while her eight-year-old called 911. Child Doe/05 had not had an episode since her hospitalization but she could go five to seven days without an episode and then have one. Jane Doe/05 also expressed concern for the effect of Child Doe/05's illness on the family, including

strain on her recent marriage. Jane Doe/05 was eager to go home and anxious for answers. *Id.* That night, Jane Doe/05 told the nurse at 10:30 p.m. that she was worried and thought in her heart that Child Doe/05 had seizures. Med. recs. at Ex. B, p. 54.

On May 24, 2001, a behavioral and developmental psychologist Dr. David Spitz saw Child Doe/05. Med. recs. at Ex. B, p. 12. Child Doe/05 had a four-week history of recurrent choking/gagging spells in which she stopped breathing. On at least one occasion, the spell occurred in the presence of a pediatric neurologist and included twitching and eye fluttering. Jane Doe/05 told Dr. Spitz that Child Doe/05 was a full-term baby with normal development. However, since the episodes began, her development had been thwarted. Jane Doe/05 was afraid to put Child Doe/05 down to attempt crawling because Child Doe/05 would roll onto her back, and Jane Doe/05 was told not to let her lie on her back. She discontinued solids because of concern about choking. Child Doe/05 appeared developmentally normal to Dr. Spitz. Jane Doe/05 noted a "staring spell" during his visit with her and Child Doe/05. *Id.*

Also on May 24, 2001, Dr. Rhodes, a pediatric cardiologist, saw Child Doe/05 to rule out a cardiac cause for her ALTE (acute life-threatening event). The history was that Child Doe/05 had 12 episodes of going limp with eyes fluttering over the last one month. There was a questionable association with feeds. Med. recs. at Ex. B, p. 13. She had had multiple hospital admissions (South Shore, Children's). The last episode occurred six days earlier. Dr. Rhodes' opinion was that a cardiovascular etiology was unlikely. *Id.* Again, Jane Doe/05 expressed her frustration that there was no medical reason identified for Child Doe/05's spells. Med. recs. at Ex. B, p. 56.

On May 25, 2001, Child Doe/05 was discharged from New England Medical Center.

Med. recs. at Ex. B, p. 32. Dr. Jeffrey Biller, a pediatric gastroenterologist, wrote the discharge summary. Child Doe/05 was an eight-month-old girl with about 12 episodes of abnormal behavior over the last month, usually occurring one time in a day. These happened while she was awake. She would either go limp with eye fluttering, turn dark red, or occasionally become stiff and arch. She slept about one hour after each episode. She had a normal EKG and echocardiogram, normal EEG, normal head CT scan, normal pH probe, and a normal LP and urine and blood cultures. She awoke with a hoarse cry. *Id.* Child Doe/05 had a pH probe showing reflux and a delayed emptying scan, both suggestive of GERD (gastroesophageal reflux disease). Med. recs. at Ex. B, p. 33. She was continued on Alimentum thickened with oatmeal and Prilosec. She was started on Erythromycin 10 mg twice a day. Her appetite remained good throughout hospitalization. She received one Glycerin suppository for constipation with good result. She developed a fever on the second day of hospitalization, treated with Tylenol and Motrin. With the fever, Child Doe/05 had congestion with a barking cough. She was treated with cool mist and considered to have a viral upper respiratory tract infection. Her spells seemed associated with her being laid supine. An H type fistula was ruled out due to a normal upper GI study. A neck film showed mild tonsillar enlargement with some enlargement of the pre-vertebral soft tissues. *Id.*

Two days later, on May 27, 2001, an ambulance was called at 8:10 a.m. to pick up Child Doe/05. Med. recs. at Ex. C, p. 86. She was alert and crying. She had a seizure lasting approximately three minutes. She had been to the hospital five times over the prior weeks and was discharged two days previously from Children's. Child Doe/05's parents said that Children's stated that Child Doe/05's seizures were due to severe reflux. They described the

seizures as having some tonic movement. She had a temperature of 101º. Child Doe/05 was alert and crying throughout transport. *Id.* Child Doe/05 was brought to South Shore Hospital Emergency Department for a possible seizure. Med. recs. at Ex. C, p. 102. Child Doe/05 arrived with her father. She had been discharged from Children's Floating Hospital two days previously where a seizure disorder was ruled out, according to John Doe/05. Now Child Doe/05 was crying with her gaze to the left. She was inconsolable and did not make eye contact. Her temperature at 8:30 a.m. was 102.5º. Dr. John Leonard was with Child Doe/05 and she was given Tylenol. Med. recs. at Ex. C, p. 103. Child Doe/05 would not take a bottle. She was resting in her father's arms and appeared quieter. Jane Doe/05 came in and refused to have Child Doe/05 catheterized. She was transferred to Children's Hospital. *Id.* The final impression was a febrile illness. Med. recs. at Ex. C, p. 104. Dr. Leonard wrote that John Doe/05 stated Child Doe/05 apparently had an apneic period approximately six weeks ago (putting onset on April 15, 2001) and, since then, had overnight admission at South Shore Hospital, three-day admission at Children's Hospital, and a recent seven-day admission at Children's Floating Hospital. Med. recs. at Ex. C, p. 105. John Doe/05 stated Child Doe/05 had a GI evaluation which showed a significant reflux, and had a neurological evaluation consisting of EEGs, neuroimaging studies, and lumbar puncture, all of which were unremarkable. He stated that, over the last six weeks, Child Doe/05 had approximately 20 episodes where she became limp and nonresponsive lasting approximately 30 seconds. John Doe/05 stated that, over the prior week, Child Doe/05 had had three episodes where she had had tonic rhythmic activity of the upper extremities. When she was at Floating Hospital about a week ago for a week, she had no seizure-like activity. She did have fevers there. John Doe/05 said Child Doe/05 had been doing

well. That day, she woke up and had a seizure. *Id.* Her temperature was 102.5º. She was crying and responsive to local stimuli. She did not have focality or tonic-clonic activity. Med. recs. at Ex. C, p. 106. Dr. Leonard's differential diagnoses were seizure, cardiac arrhythmia, syncope, apnea, transient hypoglycemia, occult infection, and febrile seizure. His clinical impression was transient altered level of consciousness consistent with seizure. *Id.* His second diagnosis was febrile illness. Med. recs. at Ex. C, p. 107. She was transferred to Children's Hospital. *Id.*

On May 27, 2001, at 12:30 p.m., Child Doe/05 entered Children's Hospital Emergency Department with both parents. They gave Dr. Karen Dull a history of episodes which began April 19, 2001. The initial episode occurred while Child Doe/05 was lying on the changing table where she turned deep red for two to three minutes. Med. recs. at Ex. C, p. 112. She was admitted to South Shore and diagnosed with reflux. One week later, she had a negative EEG. On April 25, 2001, she had three episodes lasting 30 seconds when she was admitted to Children's Hospital for three days and had a negative CT, LP, and EEG. On May 4, 2001, she had seven episodes. Her parents called the EMTs but she was not brought to the ED. On May 12, 2001, she had gasping sounds associated with feeding. On May 18, 2001, Child Doe/05 was in her jumper and had upper extremity tonic-clonic shaking for four minutes. She was admitted to New England Medical Center and started on Prilosec and Mylanta. Her formula was changed. She had an EEG, gastric emptying, and an upper GI showing mild reflux. She had a negative EKG and echocardiogram. She was home May 25, 2001. On May 26, 2001, she had one episode in the morning treated with oxygen. On May 27, 2001, she vomited once in her sleep and later had four to five minutes of tonic-clonic shaking with her head down. She appeared

sleepy, with her eyes straight ahead. She was sleepy after the event. She was taken to South Shore with 102º temperature. Her appetite was somewhat decreased. She had normal urine output. She had two episodes of diarrhea that day. On examination, she was alert and nontoxic appearing. *Id.* In the ED, a nurse saw a 30-second event when Child Doe/05 went limp and then vomited. Med. recs. at Ex. C, pp. 112-13. The neurology service was consulted and felt this was not seizure activity. She vomited twice that day and had two small episodes of diarrhea. She took some formula without vomiting. She appeared alert and smiling before discharge. Child Doe/05 was to have an outpatient continuous EEG that week. Dr. Dull's assessment was reflux, gastroenteritis, and fever. Med. recs. at Ex. C, p. 113.

Two days later, on May 29, 2001, Child Doe/05 saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 19. She had a long story of possible seizures versus reflux episodes. She went to Children's Hospital Medical Center two days earlier after having a three-five minute spell which included tonic-clonic movements of her arms. She was quite sleepy after the episode, indicating possible post-ictal episode. Children's evaluated her and sent her home pending a home EEG. Children's called yesterday and wanted her to be re-admitted but Jane Doe/05 refused. Child Doe/05 had had 14 stools since yesterday. Jane Doe/05 was worried about dehydration. Child Doe/05 also had a slight fever. She got episodes more frequently on the weekend which included staring, fluttering of the eyes, and then immediate sleeping. Dr. Johnston's impression was most likely a stomach bug on top of everything else. He advised clear liquids. He would discuss the case with Dr. Gary Hsich, a neurologist at Children's. *Id.*

On May 30, 2001, Dr. Johnston telephoned Jane Doe/05. Child Doe/05 was having fever with a gastrointestinal bug. *Id.* The day before, she had diarrhea leading to vomiting. She might

have had blood in her stool the prior night after a bowel movement. Jane Doe/05 said Child Doe/05 was doing much better that day. Her stools were less frequent and she was feeling better. Dr. Johnston offered Jane Doe/05 an appointment, but she declined. *Id.*

On June 12, 2001, Child Doe/05 saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 20. Jane Doe/05 was concerned about an ear infection. Child Doe/05 had had a 48-hour history of nasal congestion without fever, vomiting, or diarrhea. Her appetite was all right. She had a slight cough. No other family members were sick. According to Jane Doe/05, Child Doe/05's prolonged EEG was completely normal. She had been concerned about possible seizures. On physical examination, Child Doe/05's ears were gray, mobile, and shiny. Her nose showed minimal congestion. Her throat was clear. Dr. Johnston diagnosed a minor cold and provided reassurance. *Id.*

One day later, on June 13, 2001, an ambulance was called at 5:31 p.m. to pick up Child Doe/05. Med. recs. at Ex. C, p. 80. Jane Doe/05 stated that petitioner had seizure-type activity for less than two minutes. She noticed Child Doe/05 was not breathing and gave her two rescue breaths. Child Doe/05 had been fighting a cold for three days and was taking Tylenol. She was on an apnea monitor. On the way to the hospital, Child Doe/05 was responsive to pain and cried several times. She had good skin color and her skin felt warm. Her last meal was about 4:30 p.m. and she did not seem to be in any distress. She slept en route to the ER. *Id.* She was brought to South Shore Hospital Emergency Department for seizures. Med. recs. at Ex. C, p. 85. Jane Doe/05 said Child Doe/05 had been in her walker and stiffened and could not catch her breath for a couple of minutes. She was awake, crying, and consolable with feeding. Med. recs. at Ex. C, p. 73. Over the prior two months (putting onset in April), she had had 20-25 episodes.

Dr. June Hanley wrote the diagnosis was possible seizure versus reflux episode. *Id.* Both parents gave the history to Dr. Hanley. Med. recs. at Ex. C, p. 76. For the last two months, she had been having 20-25 episodes. Medical conclusions were that they were not seizures. She had a four-day EEG. The GI people after a pH probe and an upper GI were done felt that her reflux was not that bad. Neurology evaluation included a spinal tap and CT scan. Her echocardiogram was normal. Today's episode occurred an hour after feeding. Child Doe/05 was upright in her walker when Jane Doe/05 saw her eyes roll back and her face turn red. Child Doe/05 began to have generalized tremulousness, lasting seconds. She was stiff and red. She passed out and Jane Doe/05 said this lasted 10-15 minutes. *Id.* On physical examination, Child Doe/05 was very well-appearing. Med. recs. at Ex. C, p. 77. Neurologically, she had no focality and was normal. Dr. Hanly's differential diagnoses included seizure versus reflux versus benign episode versus breath-holding spell. Dr. Hsich, a neurologist at Children's Hospital, was at a loss and felt that this was probably some kind of reflux and they could do another EEG. Throughout her stay in the ER, Child Doe/05 appeared very well and fed normally. *Id.*

Five days later, on June 18, 2001, an ambulance was called to pick up Child Doe/05 who was lying on her mother's lap. Jane Doe/05 told the paramedics that Child Doe/05 had had convulsions and stopped breathing for about 45 seconds. She gave her rescue breaths. She had just finished eating when the event occurred. Med. recs. at Ex. C, p. 68. En route, Child Doe/05 became apneic but recovered when the EMT squeezed her hand. *Id.* Child Doe/05 went to South Shore Hospital Emergency Department. Med. recs. at Ex. C, p. 58. Jane Doe/05 stated Child Doe/05 had a grand mal seizure with apnea. She was awake and alert at the ER. She was transferred to Children's Hospital. *Id.* Jane Doe/05 said Child Doe/05 had seized after having a

one-ounce bottle. She gave Child Doe/05 one rescue breath. Child Doe/05 was awake, alert, looking around, and playing. Med. recs. at Ex. C, p. 59. On June 18, 2001, Dr. John Leonard at South Shore wrote that Child Doe/05 had a transient altered level of consciousness and seizure. Med. recs. at Ex. C, p. 64. She had a history of gastroesophageal reflux, apnea, and a questionable seizure disorder. Jane Doe/05 said she was feeding Child Doe/05 when she became apneic and had a generalized seizure lasting seconds. The etiology of her transient spells was unclear. She had multiple negative EEGs, LPs, and endoscopy. She had no recent fever, chills, or sweats. Jane Doe/05 denied there was any pattern of the spells. She had had six episodes in the last two days. She requested transfer to Children's Hospital. *Id.* Neurologically, Child Doe/05 was nontoxic and moving all extremities. She drank without difficulty. Jane Doe/05 was very anxious. Dr. Leonard's differential diagnoses included seizure, bradyarrhythmia, hypoxemia, Munchausen,[5] meningitis, central nervous system mass or lesion. Med. recs. at Ex. C, p. 65. Dr. Leonard discussed the case with Dr. Johnston, Child Doe/05's pediatrician. *Id.*

Jane Doe/05 said Child Doe/05 had a "true seizure" and apneic episode that morning. Med. recs. at Ex. I, p. 68. Jane Doe/05 said Child Doe/05 had been doing well until Easter 2001 when she had her first spell. Jane Doe/05 said Child Doe/05 had had 25 episodes since Easter, occurring with increasing frequency over the past month. She had three spells on Saturday and three spells on Sunday. This morning, she took one ounce of formula, burped, then began gasping and appeared as if trying to swallow. Her hands were shaking and she curled in a cat-

[5] Munchausen's syndrome is "a condition characterized by habitual presentation for hospital treatment of an apparent acute physical illness, the patient giving a plausible and dramatic history, all of which is false...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1826.

like position. She looked as if she were choking to death. Her apnea monitor beeped and Jane Doe/05 gave her two rescue breaths and called 911. Jane Doe/05 said Child Doe/05 was breathing when she gave her rescue breaths but looked like she was going to stop any minute. The episode lasted three to four minutes, per Jane Doe/05. Jane Doe/05 said she was not going home without an answer for these spells. Jane Doe/05's cousin in Utah, who is a pediatric specialist, believed reflux caused laryngospasm which caused apnea and a hypoxic seizure. All of Child Doe/05's workups had been essentially negative, most suggestive of GI reflux. Jane Doe/05 said that the gastroenterologist thought they were seizures and the neurologist thought they were reflux-related. *Id.* Child Doe/05 had not been having any fevers. Between spells, she was eating and eliminating normally. She had a history of slow GI motility. She was on Alimentum with oatmeal. Jane Doe/05 had started Child Doe/05 on some solid foods that week. She had no URI symptoms, no rashes, and no swollen glands. She was developmentally normal per Jane Doe/05. Child Doe/05 was colicky with reflux as a newborn, per Jane Doe/05, and treated with Zantac between the ages of two to five and one-half months. *Id.* Dr. Kara Gasink and Dr. David Greenes reviewed the case with Child Doe/05's pediatrician Dr. Johnston and his assessment was that Child Doe/05 had chronic reflux leading to laryngospasm leading to apnea and hypoxic seizure, with Munchausen by proxy potentially contributory. Examination showed Child Doe/05 to be alert, active, and in no distress. Differential diagnoses included GE-reflux-related laryngospasm and apnea, primary seizure disorder, and Munchausen syndrome by proxy. Med. recs. at Ex. I, p. 69. Jane Doe/05 told Dr. Sara Toomey on admission June 18, 2001 that Child Doe/05 had multiple episodes since Easter. Zantac might have helped. Reglan made Child Doe/05 fussy. She still had spells with Prilosec and Mylanta. Med. recs. at Ex. I, p. 78.

On June 19, 2001, at noon, Dr. Gary Hsich, neurologist, wrote a note. Med. recs. at Ex. I, p. 82. Child Doe/05 had been hospitalized in April for similar spells. The spells resolved when her Zantac dose was doubled. He arranged for a bedside video EEG to capture any spells. *Id.*

On June 20, 2001, Dr. Chiang at Children's Hospital Medical Center telephoned Dr. Johnston and they agreed Child Doe/05 should stay until she had an episode. She would be monitored with video as well as EEG. Jane Doe/05 was concerned they were not doing anything for Child Doe/05. The episodes sounded like events but Dr. Johnston could not tell if they were seizures or hypoxic gagging events. There was no need for medication at that point. *Id.*

On June 23, 2001, Child Doe/05 was discharged from Children's Hospital. Med. recs. at Ex. I, p. 74. Dr. Vincent Chiang wrote the discharge summary. After consultation with neurology, they placed Child Doe/05 on phenobarbital. Child Doe/05 had been on a continuous EEG monitor for signs of seizures. On hospital day 5, she had an episode of staring and unresponsiveness lasting about two to three minutes followed by a period of crying and being alert. Jane Doe/05 was clearly anxious throughout the admission. Social work and psychiatry were consulted to aid in the case. Jane Doe/05 was referred to the Coping Clinic. Child Doe/05 was discharged on phenobarbital and Pepcid. *Id.*

On July 2, 2001, Child Doe/05 saw Dr. Johnston to check her phenobarbital level. Med. recs. at Ex. A, p. 21. She had staring spells noted at Children's Hospital during her last admission and was started on 45 mg per day of phenobarbital. She had had a few staring spells but no motor activity noted. She also developed a recent rash on areas touching clothing. She did not have fever, diarrhea, or cough. She had occasional vomiting as before. Dr. Johnston diagnosed a seizure disorder and mild dermatitis. *Id.*

On January 2, 2002, Child Doe/05 saw Dr. James J. Riviello, a neurologist at Children's Hospital. Med. recs. at Ex. I, p. 172. In reviewing Child Doe/05's history, Dr. Riviello identified Child Doe/05's episodes as of two types. One type of episode was significant for choking, arching, and apnea. The other type of episode was relatively minor and involved staring and unresponsiveness for about one minute. *Id.*

On April 8, 2002, Child Doe/05 saw Dr. Johnston. Med. recs. at Ex. A, p. 28. Jane Doe/05's biggest concern was Child Doe/05's seizure disorder although she had not seized recently. Jane Doe/05 wanted to put a hold on immunizations for the time being. No immunizations were administered that day. *Id.*

On September 16, 2002, Child Doe/05 saw Dr. Johnston. Med. recs. at Ex. A, p. 30. She was still on phenobarbital for her seizure disorder, and Pepcid for reflux. Jane Doe/05 refused all immunizations at this time due to Child Doe/05's seizure disorder. *Id.*

On September 9, 2003, Child Doe/05 saw Dr. Johnston. Med. recs. at Ex. A, p. 42. Decisions were to be made about possible discontinuation of phenobarbital and possible completion of the immunization series which Jane Doe/05 was "dead set against." *Id.* "We talked about the national vaccine compensation act and how Child Doe/05 might qualify as a person who has been damaged by vaccines." *Id.*

On September 19, 2005, Child Doe/05 saw Dr. Johnston. P. Ex. R, p. 1. Child Doe/05 had a seizure disorder. "Thought to be post vaccinations seizures". *Id.* She was not administered acellular DPT or IPV "because of previous seizures presumably from vaccinations." *Id.*

On February 6, 2006, Child Doe/05 saw Dr. Cynthia Rooney, a neurologist at Children's

Hospital. Med. recs. at Ex. 21, p. 5. She last saw Child Doe/05 on October 17, 2005 and was on phenobarbital (32.4 mg tablet), half-tablet in the morning and one tablet in the evening. At the last appointment, Dr. Rooney asked Jane Doe/05 to decrease this dose, but Jane Doe/05 did not do this until mid-December. Child Doe/05 did very well with the reduction in phenobarbital. Jane Doe/05 felt that Child Doe/05's language abilities increased greatly. *Id.*

On June 19, 2006, Child Doe/05 saw Dr. Rooney again. Med. recs. at Ex. 21, p. 2. Jane Doe/05 had not decreased Child Doe/05's phenobarbital dose because she was under a lot of emotional stress at that time. Dr. Rooney told Jane Doe/05 that she would very much like to get Child Doe/05 off phenobarbital because it can interfere with a child's learning abilities. Child Doe/05 toe-walked, but her father also toe walked. *Id.*

Other submitted material

On July 27, 2004, petitioners filed the affidavit of Jane Doe/05, dated February 11, 2004. P. Ex. G. Jane Doe/05 states Child Doe/05 suffered a vaccine injury. *Id.*

On August 10, 2004, petitioners filed the second affidavit of Jane Doe/05, dated July 26, 2004. P. Ex. H. Jane Doe/05 states that within a few days of her vaccination on March 26, 2001, Child Doe/05 began to exhibit unusual behavior, beginning with periods of deep staring and erratic head movements from side to side. Jane Doe/05 states that, at times, Child Doe/05's eyes started to roll back, although this occurred only very slightly at first. Child Doe/05 also began to scream uncontrollably for extended periods of time which she had never done before. P. Ex. H, ¶ 4. Jane Doe/05 states that on Saturday, April 14, 2001, a much more dramatic event occurred at 7:30 a.m. while Child Doe/05 was being changed on a changing table. Petitioners saw Child Doe/05 turn limp, roll her eyes back in her head, and have her face turn red. They

realized she was not breathing and called 911. P. Ex. H, ¶ 5.

On December 22, 2005, petitioners filed the third affidavit of Jane Doe/05, dated December 2, 2005. P. Ex. N. Jane Doe/05 states that Child Doe/05's onset of unusual behavior was within a few days of her vaccinations of March 26, 2001. The reason Jane Doe/05 did not mention these early symptoms when she brought Child Doe/05 to the hospital on April 14, 2001 was that her symptoms at that time were so much worse and she was focused only on the current emergency. Child Doe/05 had suddenly become limp, stopped breathing, her face had turned red, and John Doe/05 had to resuscitate her. This was a life-threatening event which scared both her and John Doe/05 and they rushed Child Doe/05 to the hospital by ambulance. Jane Doe/05 had a bad headache and felt as if she were going to be sick at the hospital. Neither she nor John Doe/05 thought of the events that occurred in March. P. Ex. N, p. 1. They just wanted Child Doe/05 to be alive and well. P. Ex. N, p. 2.

On February 27, 2006, petitioners filed the fourth affidavit of Jane Doe/05, dated February 14, 2006. P. Ex. P. Jane Doe/05 says that Child Doe/05's behavior changed approximately two to three days after her vaccination on March 26, 2001. Her unusual behavior was staring and moving her head, lasting a few seconds. When asked why she did not take Child Doe/05 to her pediatrician before April 14, 2001 despite having told Dr. Jolles on December 18, 2000 (at the time of Child Doe/05's first acellular DPT vaccination) that she intended to watch Child Doe/05 closely for any reaction, Jane Doe/05 responded that either she did telephone the pediatrician's office and mention the reaction to the nurse or doctor or the unusual behavior was so brief and infrequent that, at the time, "I possibly thought it was just a one time thing." P. Ex. P, p. 1. Only after the major episodes did she look back and try to determine what was normal

and what was unusual. P. Ex. P, pp. 1-2.

On February 27, 2006, petitioners filed the affidavit of John Doe/05, dated February 14, 2006. P. Ex. O. He states that, after Child Doe/05's vaccinations on March 26, 2001 and prior to April 14, 2001, he did not notice anything abnormal about Child Doe/05 other than her crying a little more. He was working full-time. His wife noticed some strange behavior and told him about it on three occasions. She first mentioned that Child Doe/05 had seemed briefly unresponsive to her, lasting a few seconds, and that Child Doe/05 acted almost as if she were not with her, as if she were somewhere else. This occurred on March 30th or 31st. Jane Doe/05 again mentioned it to John Doe/05 on April 4th or 5th. These events lasted a few seconds and Jane Doe/05 might not have seen each of them. Afterwards, Child Doe/05 appeared fine. P. Ex. O, p. 1. Petitioners talked about calling the doctor the second time Jane Doe/05 reported the occurrence to John Doe/05, but since it seemed so minute, lasted so briefly, and Child Doe/05 was normal afterwards, they decided to wait to see if it happened again. P. Ex. O, pp. 1-2. Jane Doe/05 wanted to give it some time to see if the occurrences would pass. Just a few minutes prior to the seizures of April 14, 2001, John Doe/05 was changing Child Doe/05's diaper and he and Jane Doe/05 were discussing Child Doe/05's unusual behavior when the more serious event happened. John Doe/05 asked Jane Doe/05 if what was occurring was what Child Doe/05 had experienced before. They rushed Child Doe/05 to the emergency room. P. Ex. O, p. 2.

On December 4, 2006, petitioners filed the affidavit of Nancy F., dated October 31, 2006. P. Ex. Q. Ms. F. is a friend of Jane Doe/05 whom she has known for many years. P. Ex. Q, ¶ 2. She visited Jane Doe/05 and Child Doe/05 at their home one or two days after Child Doe/05's vaccinations of March 26, 2001. Child Doe/05 was screaming in pain and constantly crying.

She was inconsolable and nothing would calm her. Child Doe/05 got stiff and screamed. P. Ex. Q, ¶ 4. Some time in April, Ms. F. saw Child Doe/05 have staring spells where she would stare off into space, and be zoned out and blanked out. Jane Doe/05 and Ms. F. would clap their hands and call Child Doe/05's name to get her to snap out of it. Jane Doe/05 told Ms. F. that, prior to this, Child Doe/05 had been acting strangely with brief staring spells. P. Ex. Q, ¶ 5.

After the hearing on May 24, 2007 in Boston, Massachusetts, the undersigned issued an Order dated May 25, 2007 that petitioners file an affidavit from Jane Doe/05's mother, Anne Doe. On July 2, 2007, petitioners filed Anne Doe's affidavit, dated June 19, 2007. P. Ex. 25. Anne Doe states that she is very close to her daughter, Jane Doe/05, and speaks to her often, sometimes three to four times a day. P. Ex. 25, ¶ 2. Within a week or two of Child Doe/05's March 25, 2001 vaccinations, Anne Doe states she remembers speaking with Jane Doe/05 on the telephone and Jane Doe/05 told her that Child Doe/05 did a strange thing that day when she suddenly fell asleep all of a sudden. During another call at around this same time, Jane Doe/05 told Anne Doe that something really weird happened where Child Doe/05 was in her crib playing and, suddenly, she fell asleep and Jane Doe/05 could not wake her right away. She also suddenly fell asleep in her jumper. P. Ex. 25, ¶ 4. Anne Doe states that Jane Doe/05 called her another day around the same time period and said Child Doe/05 was doing it again. Anne Doe rushed over to the Jane Doe/05's house and picked Child Doe/05 up. Child Doe/05 looked at her with a smile and, the next moment, was asleep in her arms and would not wake up for a while. P. Ex. 25, ¶ 5. At Jane Doe/05's beauty shop, Anne Doe was having her hair done and Jane Doe/05 told her that Child Doe/05 did something funny that day when she suddenly dozed off and slept. P. Ex. 25, ¶ 6. Afterwards, Jane Doe/05 called Anne Doe and she was screaming,

saying that Child Doe/05 had stopped breathing. The fire department came and took her to the emergency room. P. Ex. 25, ¶ 7.

TESTIMONY

Nancy F. testified first for petitioners. Tr. at 6. She went to high school 21 years ago with Jane Doe/05. Jane Doe/05 interjected that they have been friends for longer than 21 years. Tr. at 7-8. They would visit, hang out, eat lunch together, and take walks. Tr. at 8. Ms. F.'s daughter is one year older than Jane Doe/05's older daughter, and Ms. Fleck's son is one year older than Jane Doe/05's son. Tr. at 9. Ms. F. was aware that Child Doe/05 had gastroesophageal reflux disease at the age of five weeks. *Id.* She spat up when she had formula. *Id.* A day or two after the vaccinations on March 26, 2001, Ms. F. visited Jane Doe/05 and Child Doe/05 was screaming, crying, stiff as if she were in pain. Tr. at 10-11. They could not get her to stop. Tr. at 11. She was crying uncontrollably. *Id.* Jane Doe/05 told Ms. F. she was worried and she thought it was because of the vaccinations because Child Doe/05 had been fine before and then, all of a sudden, a couple of days after the vaccinations, she was acting different. *Id.* Ms. F. believed that Jane Doe/05 had talked to her doctor about this. Tr. at 12. Ms. F. called a couple of days after, and Child Doe/05 was the same, still not herself. *Id.*

Ms. F. lived close to petitioners. Tr. at 13. In trying to explain what she meant by Child Doe/05's being stiff, Ms. F. said her hands were out and her legs were straight. Tr. at 14. Petitioners' counsel asked if Child Doe/05's body was like a board and Ms. F. agreed. Tr. at 15.

In April, Child Doe/05 had a staring spell and Ms. F. and Jane Doe/05 would clap their hands to get her out of it. *Id.* Once they made a loud noise, Child Doe/05 would come out of it. Tr. at 16. She saw Child Doe/05 about once a month, if that often. Tr. at 18. Ms. F. knew that

Child Doe/05 had recently received a vaccination because Jane Doe/05 told her. Tr. at 19. Ms. F. told Jane Doe/05 to call the doctor in March after the vaccinations. Tr. at 21.

Jane Doe/05 testified next for petitioners. Tr. at 24. Before Child Doe/05's March 26, 2001 vaccinations, Child Doe/05 was regular, that is, Jane Doe/05 did not find anything different about her. She was her third child. *Id.* Jane Doe/05 said that gastroesophageal reflux disease was not a big issue for Child Doe/05. *Id.* She said there was no medicine given to Child Doe/05 for her reflux. Tr. at 24-25. Jane Doe/05 denied that Child Doe/05 was ever diagnosed with gastroesophageal reflux disease. Tr. at 25. Child Doe/05 did throw up, but it did not change any normal daily behavior. *Id.* The records show that New England Medical Center gave her a pH probe which showed reflux and Child Doe/05 had a delayed emptying scan. Therefore, the Center diagnosed Child Doe/05 with gastroesophageal reflux disease, but Jane Doe/05 testified that the doctors could not figure out what was Child Doe/05's problem. *Id.* Then Jane Doe/05 admitted that Child Doe/05 had reflux, but so did her older daughter. Tr. at 26. All three children threw up. *Id.*

The undersigned questioned Jane Doe/05 about Child Doe/05's visit to the pediatrician Dr. Jolles on December 18, 2000 when she was to received her first acellular DPT vaccination. Tr. at 34. According to the medical records, Jane Doe/05 was concerned because her son had had a reaction to his DPT vaccination. *Id.* Jane Doe/05 testified that her son did not have a reaction to the vaccine. She stated that his only reaction was redness at the vaccine site and a fever, but he never reacted to the vaccines. *Id.* Jane Doe/05 stated she would never have had another child vaccinated if her son had had a reaction. Tr. at 34-35. The undersigned then read from the records, Exhibit A, p. 13, in which Jane Doe/05 tells Dr. Jolles that her son had a

reaction to the whole cell vaccine and became very lethargic for about two days. Her son had not received any other pertussis vaccinations. Jane Doe/05 elected to have Child Doe/05 vaccinated with acellular DPT and would watch Child Doe/05 closely for any reaction. Tr. at 35. Jane Doe/05, while denying her son had a reaction, testified he was not acting like himself but that was not like what petitioners were experiencing with Child Doe/05. *Id.* Jane Doe/05 also testified that her son finished all his vaccinations and she did not think he went without further pertussis as part of those vaccines. Tr. at 35-36. Her son was up to date with everything. Tr. at 36.

Jane Doe/05 denied she brought Child Doe/05 in to see the pediatrician just for an infected ear lobe due to an earring. She thought it probably was for something else. *Id.* She stated that she had a good pediatric practice and she called them for just about anything. Tr. at 37. She does not let her children go even a 12-hour span without taking them to get checked if there is a problem. *Id.* Jane Doe/05 lives 20 minutes from the pediatrician's office. Tr. at 38.

Child Doe/05 was fine on the trip home from the pediatrician's office on March 26, 2001 when she received her second acellular DPT vaccination. Tr. at 38-39. There was nothing unusual that day. Tr. at 39. Jane Doe/05 remembered saying to Ms. F. probably a couple of days after the vaccinations that Child Doe/05 was just not herself. She can remember clearly saying that Child Doe/05 was different and she wondered if it was something to do with her vaccinations. Tr. at 40. It was no more than four or five days after the vaccinations. *Id.* Child Doe/05 was fussy. *Id.* When the undersigned asked Jane Doe/05 to comment on Ms. F.'s testimony that Child Doe/05 was screaming bloody murder because she was in pain, Jane Doe/05 responded that she was sure that she called the doctor about that. She knows she would have

because she has such a good relationship with her pediatrician. Usually, the office would say, if there is a problem like that, just to watch her. *Id.* Jane Doe/05 said she did not like to bring Child Doe/05 to the doctor because she was "germaphobic." Tr. at 41. When one is at the pediatrician's office, the children catch something while they are waiting. *Id.*

Jane Doe/05 does not believe Child Doe/05 had a fever or she would have brought her in to the doctor, at least if it were a high fever. *Id.* Out of all the children Jane Doe/05 has, Child Doe/05 was the easiest. Child Doe/05 was very laid back and that was why it dawned on Jane Doe/05 that something was different because of the vaccines Child Doe/05 received. There was a change. She was just different. Tr. at 42. Jane Doe/05 recalled saying to Ms. F. that Child Doe/05 acted so different since she had the vaccinations. *Id.* Child Doe/05's vaccination site looked normal, not red or swollen. *Id.* Ms. F. was just with Jane Doe/05 for an hour in the morning. Tr. at 43. Child Doe/05 continued to be fussy from then on. She was different. She was not content and not sleeping as long or eating as well. She was crying a lot more. *Id.*

Jane Doe/05 testified that Child Doe/05 gradually started to get sicker and she remembered saying to her mother that Child Doe/05 was different. *Id.* Child Doe/05 was not comfortable. Tr. at 44. She took the same amount of formula in her bottle. Child Doe/05 would look at her but, when she started to daze out for a few seconds, it was different than reflux. *Id.* Jane Doe/05 knows reflux because her older daughter had it. *Id.* Her older daughter is eight years older than Child Doe/05, and her son is five years older than Child Doe/05. Tr. at 45. Child Doe/05 used the same number of diapers after March 25, 2001. *Id.* Her behavior was different because she was not comfortable, fussy, not content. Jane Doe/05 had to hold Child Doe/05 constantly. *Id.* After the vaccination, Jane Doe/05 had to buy a baby carrier because she

could not just leave Child Doe/05 and vacuum. Tr. at 46. She had to hold her. It was a completely different situation. Child Doe/05 just did not feel well. *Id.*

Jane Doe/05 recalls telephoning her pediatrician's office and saying, "It sounds ridiculous, but I can't help but say she's doing something strange or she's acting weird." *Id.* Jane Doe/05 did not remember Child Doe/05 being on Reglan. Tr. at 47. Jane Doe/05 did not know why in each of her affidavits she did not mention the screaming that Ms. F. put in her affidavit describing Child Doe/05's behavior two days after vaccination. *Id.* Then she explained that this was such a bad situation and so long ago, but then it was not long ago at all but an every day worry, that maybe she did not describe the screaming, but she remembered it very clearly. Tr. at 48.

In Jane Doe/05's affidavit of February 14, 2005, she described the change in Child Doe/05's behavior as staring and moving her head, lasting a few seconds, occurring two or three days after vaccination. In her testimony, Jane Doe/05 agreed with her prior description and said it was just a weird jerk. *Id.* She telephoned her mother and told her that Child Doe/05 did something so strange; she just fell asleep so quickly in her crib. *Id.*

When the undersigned read to Jane Doe/05 her answer in her affidavit dated December 2, 2005 to the question why she did not tell anyone about Child Doe/05's early symptoms when she and her husband brought Child Doe/05 to the hospital on April 14, 2001 because her symptoms on April 14th were so much worse, Jane Doe/05 denied that she did not mention the early symptoms. It was just that she could not explain them. She said you cannot explain a five-second stare unless you saw it. Tr. at 48-49. Petitioners' counsel mentioned that in paragraph 4 of Jane Doe/05's affidavit of July 26, 2004 (Ex. H), she mentioned that Child Doe/05 began to

scream uncontrollably for extended periods of time within a few days of her March 26, 2001 vaccinations. Tr. at 51. Aside from Child Doe/05's screaming, her other symptoms were very subtle, including 10 seconds of staring. Tr. at 51.

On cross-examination, respondent's counsel asked Jane Doe/05 about her testimony that Child Doe/05 was her easiest child out of the three, by which she meant having a good temperament and not crying much. Tr. at 60. Counsel read from Ex. A, p. 8., a telephone call to Dr. Johnston that Jane Doe/05 made on October 16, 2000 when Child Doe/05 was five weeks old that Child Doe/05 was very colicky and still quite fussy. Tr. at. 61. Jane Doe/05 testified that if Child Doe/05 were fussy, she is sure she would have called. *Id.* Jane Doe/05 does not remember Child Doe/05 being that bad with reflux unlike her older daughter. Tr. at 62. When respondent's counsel read Jane Doe/05 the note for a sick visit to Dr. Johnston on October 17, 2000 (Ex. A, p. 6) that Child Doe/05 had been fine until she was three weeks of age and the last couple of weeks had been miserable with Child Doe/05 up every night crying, very colicky, pulling her legs up and refluxing with spitting almost every feeding, especially at night, Jane Doe/05 testified that Child Doe/05 was never diagnosed with reflux. *Id.* She thought that doctors always diagnose colic when a baby cries. *Id.* When respondent's counsel continued with Dr. Johnston's impression that Child Doe/05's symptoms were very compatible with gastroesophageal reflux, Jane Doe/05 replied that Child Doe/05 was not diagnosed with reflux. Tr. at 62-63.

Respondent's counsel read from a sick visit on November 1, 2000 when Child Doe/05 was seven weeks old (Ex. A, p. 10), which describes Child Doe/05 as still miserable, but no more than before, and she had a cold and cough. Tr. at 63. Jane Doe/05 responded that Child

Doe/05 may have had intermittent crying with a bellyache, but this was different than what happened after the vaccinations. Tr. at 64. Jane Doe/05 testified that she believed she called Dr. Johnston a couple of days after the vaccinations. She asserted that she knew she did. *Id.*

Respondent's counsel asked Jane Doe/05 if she recalled bringing Child Doe/05 to South Shore Hospital Emergency Room on November 1, 2000, and she said she did. It was for the croup. *Id.* She said the circumstances were nothing compatible [perhaps she meant comparable] to Child Doe/05's post-vaccination condition. Tr. at 65. Child Doe/05 did not stop breathing on November 1, 2000. Jane Doe/05 said she probably overreacted and needed to make sure Child Doe/05 was fine because she was so small. *Id.* [The medical records show that petitioners brought Child Doe/05 in to the ER because Child Doe/05 had difficulty breathing. Ex. C, pp. 212, 213.]

Jane Doe/05 testified that she did not recall anything being wrong with Child Doe/05 until March 2001. Tr. at 66. Both of her other children had colic which can go on for a long time with crying and screaming, but that is nothing and does not bother her. What bothered her is when she could not run to the supermarket because there was no one to watch Child Doe/05 because they were afraid to watch her. Tr. at 66-67.

When respondent's counsel moved to the December 18, 2000 visit to the pediatrician's office (Ex. A, p. 13) which that day was with Dr. Jolles, Jane Doe/05 denied that she had seen Dr. Jolles because she always saw Dr. Johnston. Tr. at 67. There was nothing to remember about Child Doe/05's first acellular DPT vaccination. *Id.* When the undersigned questioned Jane Doe/05 about her denial of seeing Dr. Jolles on December 18, 2000, she reiterated that she was almost positive that Child Doe/05's appointments were with Dr. Johnston. *Id.* When the

undersigned asked why Dr. Jolles signed the December 18, 2000 medical record, Jane Doe/05 said she did not know, unless Dr. Johnston was away. Tr. at 67-68. Then she retracted and said she did not think Child Doe/05 saw Dr. Jolles more than twice. Tr. at 68. The undersigned asked about Jane Doe/05's visit with nurse practitioner Katherine Dennehy on December 7, 2000 during which Jane Doe/05 described Child Doe/05 as having congestion for two days. *Id.* N.P. Dennehy writes that Child Doe/05 was fussy but she was always fussy, conveying to the undersigned that Child Doe/05 was a fussy child. Tr. at 69. Jane Doe/05 tried to explain that she had had such a bad experience with her older daughter who cried for months and then stopped that Child Doe/05 seemed to her very easy. *Id.* To Jane Doe/05, "fussy" does not mean screaming and crying all day long. *Id.*

Respondent's counsel turned to March 26, 2001, the second acellular DPT vaccination and Jane Doe/05's testimony that everything was fine that day and the next day. *Id.* Within a few days, Child Doe/05 was crying and not herself. Tr. at 70. She had side to side movements of her head for a few seconds which was weird. If this had happened before March, she would have known. *Id.* Jane Doe/05 was absolutely sure that Child Doe/05 had erratic head movements within a few days of her March 26, 2001 vaccinations. Tr. at 71. She remembered quick staring spells and possibly her eyes moving back, but it was April when they were really rolling back because if that had happened earlier, she would have called the ambulance. It was just very gradual and very different from day to day. *Id.* What happened was a quick 10-second stare or her head moving side to side or falling asleep quickly. Jane Doe/05 would shake Child Doe/05 a bit. *Id.* The doctors were not sure what it was because they could not see it. Tr. at 72.

When the undersigned asked Jane Doe/05 about erratic head movements, Jane Doe/05

said they were not quick but slow. Tr. at 73-74. Her head would just move from side to side. Tr. at 74. It was almost as if her head was doing something her body was not doing. Her head would just jerk from side to side. *Id.* In the infant carrier, Child Doe/05 would move her head from one side to the other side very slowly. Tr. at 75. Jane Doe/05 said that "being a mother, honestly, you know when there's something the matter." Tr. at 78. John Doe/05 accompanied Jane Doe/05 to the hospitals. *Id.*

When the undersigned asked Jane Doe/05 about her history to Dr. Baum on April 14, 2001 that Child Doe/05 had two prior episodes that week of not being responsive, Jane Doe/05 said she could remember it as if it were yesterday. *Id.* It could have been a couple of weeks prior to that that things were different. It was gradual. Tr. at 79.

Jane Doe/05 remembered telling someone at her hair salon that Child Doe/05 did something different. *Id.* Jane Doe/05 did believe she called the pediatrician after the vaccinations and may have had a brief conversation. Tr. at 80. She probably spoke to a nurse. Tr. at 81. She recalled talking to her mother about it that morning, too. *Id.* She talks to her mother every morning, but it was a couple or a few days after the vaccinations when she spoke to her. *Id.*

Jane Doe/05 said that, on April 14, 2001, she thinks she was so freaked out that she probably did not think about anything else that morning. Tr. at 82. She explained that she did not take Child Doe/05 to the doctor after the vaccinations until April 14, 2001 because she probably overlooked Child Doe/05's unresponsiveness for a couple of seconds as just something weird. Tr. at 83. She is sure that she mentioned to the doctors that Child Doe/05's health took a turn for the worse after her vaccinations, specifically Dr. Johnston. *Id.* Jane Doe/05 explained

her giving a history that Child Doe/05 was well until April 14th, that it did not mean things were not different after March 26th. Tr. at 87. She reiterated that Child Doe/05 changed slowly but surely after her vaccinations in March. Tr. at 92. It was the normal practice for petitioners to go to the hospital with Child Doe/05. Tr. at 94. She said the reason she did not bring Child Doe/05 in after the March 26th vaccinations was that she did not have a fever. Tr. at 95. Jane Doe/05 testified that she knows the vaccine did this to Child Doe/05. Tr. at 96.

Jane Doe/05 made another attempt to explain why every single history she and her husband gave on and after April 14, 2001 omits any mention of screaming and unresponsiveness and head-turning after the March 26, 2001 vaccinations:

> You could call the doctor and say she's screaming and what are they going to say? They're not going to make you bring her there. I mean, if her eyes–if she was staring or her head were subtly turning, I could call or bring her there and they're not going to see it anyway. So I tried to carry on with my everyday living, hoping that it was something out of the ordinary that was going to change. I am a very–I take my kids to the doctor even when they don't need to go if they really, really, really don't look right or don't feel right. She would've been there. I thought maybe it was just the different–something just weird. Just a fluky thing.

Tr. at 100. [Jane Doe/05, however, did not answer why she and/or her husband did not give this history to any doctor on or after April 14, 2001.] Jane Doe/05 then denied that she thought at the time Child Doe/05 was turning her head or crying that she thought the vaccinations were the cause. Tr. at 101. However, she remembered saying that Child Doe/05 had not acted right since her vaccinations. *Id.* Child Doe/05 was not screaming and rolling her head at the same time. She would cry and then stare. Tr. at 106.

John Doe/05, Child Doe/05's father, testified next for petitioners. Tr. at 108. On April 14, 2001, John Doe/05 was doing a change of Child Doe/05's diaper on the changing table at

7:30 or 7:45 a.m. and talking to Jane Doe/05 who mentioned that Child Doe/05 had done a funny thing the day before or maybe a couple of days before during a walk. *Id.* Child Doe/05 looked like she was staring. At that moment, Child Doe/05 had started to do something weird and John Doe/05 picked her up and asked Jane Doe/05 if what she had described was anything like that. Tr. at 109. Child Doe/05 was lifeless, eyes rolled back, and head flopped to the right. Jane Doe/05 took Child Doe/05 and tried to pat her on the back, but she did not respond. He immediately called 911. He took Child Doe/05 from Jane Doe/05. Child Doe/05's face was dark reddish. Her gave her a couple of rescue breath on the carpet, and the paramedics were at the door. Child Doe/05 was breathing and yawning. Tr. at 110.

John Doe/05 remembers Child Doe/05 not sleeping well, being fussy and colicky and spitting up before March 26, 2001, but he said she was a fairly easy baby. Tr. at 110-11. He said that Jane Doe/05 would always feel the pain of her child. Tr. at 113. [This was John Doe/05's way of answering whether Jane Doe/05 had ever told him that her son had a reaction to his DPT and was never given pertussis again.] She would always do what Dr. Johnston said. *Id.*

John Doe/05 thinks he noticed Child Doe/05 being a little fussy two to three days after her March 26, 2001 vaccinations. Tr. at 114. Jane Doe/05 told him she thought Child Doe/05 was crying a lot more since the vaccinations. They agreed that if Child Doe/05 did not improve by the beginning of the following week, Jane Doe/05 would call the doctor. *Id.* [John Doe/05 thought that March 26, 2001 was a Thursday, but it was actually a Monday. The beginning of the next week would then have been April 2, 2001.] John Doe/05 did not see anything else prior to April 14, 2001. Tr. at 115. Jane Doe/05 had mentioned to him a couple of times that Child

Doe/05 was staring. *Id.* He did not think he could say that Child Doe/05 was a different baby between March 26 and April 14, 2001. Tr. at 116-17. He thinks that Jane Doe/05 mentioned an episode the following week after the March 26, 2001 vaccinations where Child Doe/05 was kind of staring and then, three or four days later, another episode. Tr. at 117-18.

John Doe/05 insisted that he and Jane Doe/05 gave histories to the doctors and nurses that Child Doe/05 had been experiencing something strange or different since the end of March. Tr. at 119. "And we absolutely would've mentioned and did mention previous staring episodes." *Id.* He mentioned giving a history which is in the records of his mentally retarded brother that had a seizure. *Id.* But until Child Doe/05 was diagnosed with a seizure in June 2001, John Doe/05 said that they were never in a confident, comfortable frame of mind to give accurate details. Tr. at 120. Child Doe/05's initial staring spells were subtle and minute. Tr. at 127. He thought it was a fair history that two prior episodes the week of the April 14th episode had occurred. Tr. at 128. He thinks it was Jane Doe/05 who gave that history and that she was trying to piece together the most recent events. Tr. at 129. John Doe/05 said he has learned from the Internet that vaccinations cause different behavior in children. Tr. at 131.

John Doe/05 testified that Jane Doe/05 told him the weekend after the March 26, 2001 vaccination that the vaccine was the cause. *Id.* That was before any doctor brought up the vaccinations in June or July. *Id.* Child Doe/05 never had a fever. Tr. at 133-34.

DISCUSSION

The issue of onset was the focus of the hearing because of the discrepancy between the multiple histories both parents gave to the doctors, and because petitioner's expert neurologist, Dr. Jacobson, posits his opinion on an onset occurring within one week, whereas the earliest

onset of Child Doe/05's purported seizures was the week of April 8, 2001, or 13 days after vaccination.

The law is clear that when there is a discrepancy between the contemporaneous history given in the medical records and the testimony and affidavits given after litigation has begun, the history given contemporaneously is more credible because it is given closer in time to the actual events when there is strong motivation to be truthful in order to obtain an accurate diagnosis and effective treatment compared to a history given years later, when memories have faded and the impetus to succeed in litigation may cloud memories or conflate events.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Petitioners have been through an ordeal with Child Doe/05's episodic events, occasioning

numerous, frustrating visits to the emergency rooms of and admissions to various hospitals until Child Doe/05 received phenobarbital in June 2001 which ended the episodes. This experience has no doubt influenced them in increasing the stress throughout the entire family.

Certainly, there could be no more vigilant a mother than Jane Doe/05, to her credit. She puts the health of her children above all else. She is not shy about demanding and receiving medical attention for her children's slightest problem. But she has a selective memory and her testimony not only was at odds with the histories she and her husband gave multiple times to many doctors, but she also denies the histories she gave concerning Child Doe/05 before the vaccinations at issue.

Jane Doe/05 denied that Child Doe/05's pre-March 26, 2001 behavior was difficult. Yet, between Child Doe/05's date of birth on September 8, 2000 and her March 26, 2001 vaccinations, Jane Doe/05 brought Child Doe/05 in to see the doctor or to the hospital 10 separate times[6] and telephoned the pediatrician's office six times.[7] That is the space of six and one-half months. Including two well-baby visits[8] when Child Doe/05 actually was well, Jane Doe/05 brought Child Doe/05 in for medical attention 12 times in six and one-half months, in addition to six phone calls. This is a huge amount of visits and contacts.

Jane Doe/05 denied that Child Doe/05 had ever had breathing problems before her post-March 26, 2001 vaccinations, but the medical records establish that Child Doe/05 had trouble breathing when she was brought in for croup/bronchiolitis at seven weeks.

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[6] The visits were 9/20/00, 9/28/00, 10/17/00, 11/1/00, 11/2/00, 11/14/00, 11/18/00, 12/7/00, 1/2/01, and 1/17/01.

[7] The calls were 10/2/00, 10/16/00, 11/3/00, 11/6/00, 11/9/00, and 1/12/01.

[8] The well-baby visits when Child Doe/05 was well were on 1/23/00 and 3/26/01.

Jane Doe/05 denied telling Dr. Jolles (whom she at first denied even seeing) on December 18, 2000, when it was time for Child Doe/05's first acellular DPT vaccination, that her son had had a reaction to his DPT vaccination and she was concerned about Child Doe/05's responding similarly. Jane Doe/05 not only denied telling Dr. Jolles about this reaction, she denied that her son had ever had a reaction beyond a red and swollen vaccination site. (The history she gave to Dr. Jolles was that her son had two days of lethargy after his DPT vaccination.) She also denied that her son had not received any future pertussis vaccinations. Of interest is that Dr. Jolles wrote at the end of the medical record that Jane Doe/05 said she would watch Child Doe/05 closely after the vaccination to see if she reacted. (She did not react.)

For the undersigned to accept that Jane Doe/05 never gave this history to Dr. Jolles is inconceivable. There is no earthly reason for the undersigned to believe that Dr. Jolles imagined this conversation with Jane Doe/05, that her son did not have two days of lethargy after his whole-cell DPT vaccination, that her son continued to receive more pertussis vaccinations, that Dr. Jolles did not give Jane Doe/05 information about the difference between whole-cell and acellular DPT, that Dr. Jolles did not tell Jane Doe/05 he could not promise that Child Doe/05 would not have a neurologic reaction to the DPT, and that Jane Doe/05 did not say she would be watching Child Doe/05 carefully after vaccination to see if she had a reaction. This conversation occurred and the consequence of this conversation is the natural expectation that Jane Doe/05, a truly vigilant and attentive mother, would be extra observant about Child Doe/05's behavior after vaccination because of her prior experience with her son's reaction to his DPT vaccination.

Jane Doe/05 denied in her testimony that Child Doe/05 had ever been diagnosed with reflux, but Dr. Johnston diagnosed Child Doe/05 with reflux when she was five weeks old and

various treaters continued that diagnosis repeatedly in the medical records. Child Doe/05 was constantly changing formulas. She was constantly spitting up. She was also colicky. She took Zantac as medication for her reflux, although Jane Doe/05 denied in her testimony that Child Doe/05 had ever received medication for reflux.

Jane Doe/05 testified that Child Doe/05 was laid back and was her easiest child among the three she has. But the history she gave to N.P. Dennehy was that Child Doe/05 was miserable and she was always miserable. Child Doe/05 cried, had trouble sleeping, and constantly spit up. Jane Doe/05 was afraid to feed her solid food because of Child Doe/05's difficulty ingesting. Jane Doe/05 made sure never to lay Child Doe/05 flat. This is not an easy or laid back child. And that does not include her bronchiolitis at the age of seven weeks when she had trouble breathing.

Nancy F., Jane Doe/05's close friend from before high school (whom she sees on a regular basis), testified that two days after the March 26, 2001 vaccinations, Child Doe/05 was screaming, stiff as a board, and in pain. In only one of Jane Doe/05's five affidavits did Jane Doe/05 describe Child Doe/05 as screaming after the vaccinations. But there is no visit or telephone call to Dr. Johnston from March 26, 2001 until April 17, 2001, even though Jane Doe/05 at first testified that she brought Child Doe/05 in or at least telephoned Dr. Johnston's office as soon as Child Doe/05 began screaming and/or staring. Ms. F. testified that Jane Doe/05 told her Child Doe/05 was reacting to her vaccinations, although Jane Doe/05, during her testimony, denied saying that to Ms. F.

It is extremely unlikely that Jane Doe/05, who brought Child Doe/05 in to see Dr. Johnston for an infected ear lobe in January 2001, would not telephone or bring Child Doe/05 in

when she was having a reaction to her vaccinations, especially in light of her fear, expressed to Dr. Jolles on December 18, 2001, that Child Doe/05 would react to DPT because her half-brother had reacted to DPT, and her promise to watch Child Doe/05 closely after vaccination with DPT..

Of importance, Jane Doe/05 testified that she is very close to her mother, Anne Doe. In her affidavit, Anne Doe states that she speaks to her daughter three or four times a day. She says the first time Jane Doe/05 told her that Child Doe/05 was behaving strangely was one to two weeks after the vaccinations. Anne Doe does not mention screaming, crying, and stiffness two or three days after the vaccinations. She does not mention strange staring spells lasting seconds, or turning of the head slowly, or head jerking, all occurring within two or three days after the vaccinations. Anne Doe's affidavit is consistent with an onset of these staring episodes at the earliest on April 8th (the Sunday before the Saturday, April 14th admission), which was 13 days after the March 26, 2001 vaccinations. Her affidavit is also consistent with Child Doe/05's not having a screaming and stiffening reaction to her vaccinations.

Jane Doe/05 never explained satisfactorily why she did not bring Child Doe/05 in to see Dr. Johnston or at least telephone him within two or three days of the vaccinations. At first, she said she did telephone him or one of the nurses. But there is no record of a telephone call and Dr. Johnston's office reliably records telephone calls such as the six phone calls Jane Doe/05 made to his office between Child Doe/05's birth and her March 26, 2001 vaccinations. Then Jane Doe/05 said that Child Doe/05's movements were so subtle and everything was so gradual, that she just waited for these weird (her word) movements to go away. It seems extremely unlikely that Jane Doe/05 would let any of her children have a medical problem and then just wait for it to go away. In addition, the screaming and stiffening that preceded the staring spells

and the purported additional crying were hardly subtle.

When asked why, in the numerous histories petitioners gave to the doctors on and after April 14, 2001, neither one gave a history that Child Doe/05 had this screaming, stiffening behavior followed by excessive crying, staring spells, and either slow or jerky (Jane Doe/05 testified to both) head turning within days of her March 26, 2001 vaccinations, Jane Doe/05 said she just could not recall it in the stress of the moment while John Doe/05 said they did tell the doctors. What the records show is that the doctors asked if Child Doe/05's immunizations were up to date, and the Does answered no because her bronchiolitis at age seven weeks delayed her vaccinations. This would have been a perfect time for Jane Doe/05 to mention that Child Doe/05's episodes actually began two or three days after her March 26, 2001 vaccinations, consisting of non-stop screaming, stiffening, staring, and head turning, not that the onset was two episodes occurring the week of April 14, 2001, including one the day before the April 14th episode.

When asked how Child Doe/05's health had been before the mid-April 2001 onset of episodes, both parents told the hospital personnel that Child Doe/05 was fine except for reflux and bronchiolitis. This also would have been a perfect time for them to give a history that Child Doe/05 had "weird" spells where she zoned out for a few seconds or turned her head either slowly or jerkily, starting in late March 2001. But they gave no such history, although John Doe/05 testified that they gave that history. His testimony on that point is not credible. It is inconceivable that the doctors would write voluminous notes on Child Doe/05's pre-April 14th history but omit that she had been having staring spells since two or three days after her March 26, 2001 vaccinations and that she had experienced an increase of crying following her

screaming and stiffening two or three days after her March 26, 2001 vaccinations.

Between April 14, 2001 and the end of June, petitioners saw an astounding number of medical personnel and never told one of them about screaming, stiffening, increased crying, staring spells, and waving or jerking of Child Doe/05's head two or three days after the March 26, 2001 vaccinations. Between April 14, 2001 and the end of June 2001, petitioners saw: Dr. Michael Hughes, Dr. Carol Baum, Dr. Heather McLaughlan, Dr. David Greenes, Dr. Gary Hsich, Dr. Jonathan Megerian, Dr. Randi Pleskow, Dr. Dwayne Greene, Dr. Stuart Harris, Dr. Marvin Harper, Dr. Rhodes, Dr. Uzme Vhang, Dr. John Leonard, Dr. Feigall, Dr. M. Provenca, Dr. Jeffrey Biller, Dr. Karen Dull, Dr. June Hanly, Dr. Kara Gasink, Dr. Sara Toomey, Dr. Vincent Chiang, and Dr. James Riviello, besides the psychologist Dr. David Spitz and the case worker Cara Weiner (and these are the names the undersigned could decipher from the medical records). To none of these 24 people did petitioners divulge that the onset of Child Doe/05's spells began at the end of March or two to three days after her March 26, 2001 vaccinations because that information is not in one single record.

One would also expect that Dr. Johnston, whom Jane Doe/05 and Child Doe/05 saw on April 17, 2001, would have written in his records that Child Doe/05 had experienced screaming, stiffening, increased crying, and staring spells with head waving or jerking within two or three days of her March 26, 2001 vaccinations when Jane Doe/05 and Child Doe/05 saw him. But there is no such record. Dr. Johnston has been a faithful recorder (as has Dr. Jolles) of Jane Doe/05's complaints about Child Doe/05's health problems since Child Doe/05's birth. It is inconceivable that if Jane Doe/05 had given him this history on April 17, 2001, or telephoned him two to three days after the March 26, 2001 vaccinations, he or a nurse would not have

written this information down. The only reasonable conclusion is that Jane Doe/05 did not give him this history for another two and one-half years when she decided Child Doe/05 had reacted to her vaccinations.

On April 8, 2002, 13 months after the onset of Child Doe/05's seizures, Jane Doe/05 told Dr. Johnston that she did not want to have Child Doe/05 vaccinated that day. This is the first record showing Jane Doe/05's aversion to further vaccination.

On September 16, 2002, one and one-half years after the onset of seizures, Jane Doe/05 told Dr. Johnston that she did not want Child Doe/05 vaccinated because of Child Doe/05's seizure disorder. This record still does not contain a history that Child Doe/05 reacted to her last vaccinations. It would not be unreasonable to keep someone with a seizure disorder from being vaccinated. According to the record of December 18, 2000, Jane Doe/05 had never let her son receive further pertussis vaccinations after his reaction to whole-cell DPT vaccine. She denied this ever happened in her testimony, however. Her testimony is not credible.

Not until September 9, 2003, two and one-half years after Child Doe/05's onset of seizures, is there a notation in Dr. Johnston's records of Jane Doe/05 having a discussion with him about Child Doe/05's possibly having a vaccine injury claim.

John Doe/05 testified that Jane Doe/05's relationship to Dr. Johnston was guru-like. It would only be reasonable that, if Child Doe/05 had reacted to her March 26, 2001 vaccinations with screaming, stiffening, excessive crying, followed by staring spells and head waving or jerking, that Jane Doe/05 would seek help from the doctor to whom she was so close and tell him immediately after the onset of Child Doe/05's seizures, if they had occurred two or three days post-vaccination, that his office had given Child Doe/05 the second DPT and look what

happened: screaming, stiffening, crying, a changed baby, an unwell child, staring episodes, jerking or slow turning of her head. She had warned Dr. Jolles of her concern on December 18, 2000 and had said she would watch Child Doe/05 closely after her DPT vaccination.

The only explanation for Jane Doe/05's failure to tell Dr. Johnston immediately about what Child Doe/05 was experiencing purportedly within two or three days of her second acellular DPT is that she did not have screaming, stiffening, and excessive crying, and that the onset of Child Doe/05's staring spells occurred weeks later, no earlier than 13 days later. Jane Doe/05 did not associate the staring spells with the March 26, 2001 vaccinations until years had passed and she had conflated the timing of the spells with the date of the vaccinations. The history that the Does gave to more than 24 hospital personnel and doctors from April through June 2001 was accurate. Child Doe/05 began having two staring episodes the week of April 8, 2001 (one of which was on April 13, 2001) culminating in the third spell of a stoppage of breathing on April 14, 2001 and there was nothing untoward in her prior medical history other than gastroesophageal reflux, colic, and bronchiolitis.

The undersigned holds that the onset of Child Doe/05's spells after her March 26, 2001 vaccinations was no earlier than April 8, 2001, which is 13 days post-vaccination.

The undersigned also holds that Child Doe/05 did not have any unusual behavior, such as screaming, stiffening, crying out in pain, or becoming a different child, within days of Child Doe/05's March 26, 2001 vaccinations. Jane Doe/05 would have taken Child Doe/05 to the doctor or at least called his office, particularly in light of her concern over her son's reaction to DPT. Moreover, Jane Doe/05 would have told her mother with whom she was in frequent and daily telephone contact if this had actually occurred and she did not. Her testimony and that of

her close friend Nancy F. is not credible.

Since Jane Doe/05 denied in her testimony that Child Doe/05 ever had gastroesophageal reflux and petitioners' counsel waffled over whether petitioners are now alleging that Child Doe/05 had seizures starting at five weeks (when Dr. Johnston first diagnosed gastroesophageal reflux), which precedes the March 26, 2001 vaccinations, the parties are ORDERED to do the following:

1. Send a copy of this Ruling on Onset to their respective experts (Dr. Jacobson and Dr. Johnston for petitioners; Dr. Wiznitzer for respondent).

2. (a) File by **Monday, September 17, 2001,** supplemental reports from the medical experts Drs. Jacobson, Johnston, and Wiznitzer answering whether they think that Child Doe/05 never had gastroesophageal reflux but always had seizures, starting at five weeks, and if so, the basis for their opinion. If they believe that Child Doe/05's seizures began before her March 26, 2001 vaccinations, then petitioners must be alleging that the March 26, 2001 vaccinations significantly aggravated her pre-existing seizure disorder. The medical experts Drs. Jacobson, Johnston, and Wiznitzer shall include in their supplemental reports their opinion whether the March 26, 2001 vaccinations significantly aggravated her pre-existing seizure disorder and, if so, the basis for their opinion.

(b) If the medical experts Drs. Jacobson, Johnston, and Wiznitzer do not believe that Child Doe/05 had a seizure disorder before March 26, 2001, in light of the undersigned's holding that the onset of her spells was no earlier than April 8, 2001 (13 days post-vaccination), the medical experts Drs. Jacobson, Johnston, and Wiznitzer shall include in their supplemental

reports whether or not they believe that the March 26, 2001 vaccinations caused Child Doe/05's spells 13 or more days later and, if so, the basis for their opinions.

IT IS SO ORDERED.

Dated:_____ _____

Laura D. Millman
Special Master